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Psychological therapies for temporomandibular disorders (TMDs) (Review)

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Psychological therapies for temporomandibular disorders (TMDs).
Cochrane Database of Systematic Reviews 2022, Issue 8. Art. No.: CD013515.
DOI: 10.1002/14651858.CD013515.pub2.

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[Intervention Review]

Psychological therapies for temporomandibular disorders (TMDs)

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Editorial group: Cochrane Oral Health Group.
Publication status and date: New, published in Issue 8, 2022.

Citation: Penlington C, Bowes C, Taylor G, Otemade AA, Waterhouse P, Durham J, Ohrbach R. Psychological therapies for temporomandibular disorders (TMDs). *Cochrane Database of Systematic Reviews* 2022, Issue 8. Art. No.: CD013515. DOI: 10.1002/14651858.CD013515.pub2.

ABSTRACT

Background

Temporomandibular disorders (TMDs) are a group of musculoskeletal disorders affecting the jaw. They are frequently associated with pain that can be difficult to manage and may become persistent (chronic). Psychological therapies aim to support people with TMDs to manage their pain, leading to reduced pain, disability and distress.

Objectives

To assess the effects of psychological therapies in people (aged 12 years and over) with painful TMD lasting 3 months or longer.

Search methods

Cochrane Oral Health's Information Specialist searched six bibliographic databases up to 21 October 2021 and used additional search methods to identify published, unpublished and ongoing studies.

Selection criteria

We included randomised controlled trials (RCTs) of any psychological therapy (e.g. cognitive behaviour therapy (CBT), behaviour therapy (BT), acceptance and commitment therapy (ACT), mindfulness) for the management of painful TMD. We compared these against control or alternative treatment (e.g. oral appliance, medication, physiotherapy).

Data collection and analysis

We used standard methodological procedures expected by Cochrane. We reported outcome data immediately after treatment and at the longest available follow-up.

We used the Cochrane RoB 1 tool to assess the risk of bias in included studies. Two review authors independently assessed each included study for any risk of bias in sequence generation, allocation concealment, blinding of outcome assessors, incomplete outcome data, selective reporting of outcomes, and other issues. We judged the certainty of the evidence for each key comparison and outcome as high, moderate, low or very low according to GRADE criteria.

Main results

We identified 22 RCTs (2001 participants), carried out between 1967 and 2021. We were able to include 12 of these studies in meta-analyses. The risk of bias was high across studies, and we judged the certainty of the evidence to be low to very low overall; further research may change the findings. Our key outcomes of interest were: pain intensity, disability caused by pain, adverse events and psychological

distress. Treatments varied in length, with the shortest being 4 weeks. The follow-up time ranged from 3 months to 12 months. Most studies evaluated CBT.

At treatment completion, there was no evidence of a benefit of CBT on pain intensity when measured against alternative treatment (standardised mean difference (SMD) 0.03, confidence interval (CI) -0.21 to 0.28; P = 0.79; 5 studies, 509 participants) or control (SMD -0.09, CI -0.30 to 0.12; P = 0.41; 6 studies, 577 participants). At follow-up, there was evidence of a small benefit of CBT for reducing pain intensity compared to alternative treatment (SMD -0.29, 95% CI -0.50 to -0.08; 5 studies, 475 participants) and control (SMD -0.30, CI -0.51 to -0.09; 6 studies, 639 participants).

At treatment completion, there was no evidence of a difference in disability outcomes (interference in activities caused by pain) between CBT and alternative treatment (SMD 0.15, CI -0.40 to 0.10; P = 0.25; 3 studies, 245 participants), or between CBT and control/usual care (SMD 0.02, CI -0.21 to 0.24; P = 0.88; 3 studies, 315 participants). Nor was there evidence of a difference at follow-up (CBT versus alternative treatment: SMD -0.15, CI -0.42 to 0.12; 3 studies, 245 participants; CBT versus control: SMD 0.01 CI - 0.61 to 0.64; 2 studies, 240 participants).

There were very few data on adverse events. From the data available, adverse effects associated with psychological treatment tended to be minor and to occur less often than in alternative treatment groups. There were, however, insufficient data available to draw firm conclusions.

CBT showed a small benefit in terms of reducing psychological distress at treatment completion compared to alternative treatment (SMD -0.32, 95% CI -0.50 to -0.15; 6 studies, 553 participants), which was maintained at follow-up (SMD -0.32, 95% CI -0.51 to -0.13; 6 studies, 516 participants). For CBT versus control, only one study reported results for distress and did not find evidence of a difference between groups at treatment completion (mean difference (MD) 2.36, 95% CI -1.17 to 5.89; 101 participants) or follow-up (MD -1.02, 95% CI -4.02 to 1.98; 101 participants).

We assessed the certainty of the evidence to be low or very low for all comparisons and outcomes.

The data were insufficient to draw any reliable conclusions about psychological therapies other than CBT.

Authors' conclusions

We found mixed evidence for the effects of psychological therapies on painful temporomandibular disorders (TMDs). There is low-certainty evidence that CBT may reduce pain intensity more than alternative treatments or control when measured at longest follow-up, but not at treatment completion. There is low-certainty evidence that CBT may be better than alternative treatments, but not control, for reducing psychological distress at treatment completion and follow-up. There is low-certainty evidence that CBT may not be better than other treatments or control for pain disability outcomes.

There is insufficient evidence to draw conclusions about alternative psychological therapeutic approaches, and there are insufficient data to be clear about adverse effects that may be associated with psychological therapies for painful TMD.

Overall, we found insufficient evidence on which to base a reliable judgement about the efficacy of psychological therapies for painful TMD. Further research is needed to determine whether or not psychological therapies are effective, the most effective type of therapy and delivery method, and how it can best be targeted. In particular, high-quality RCTs conducted in primary care and community settings are required, which evaluate a range of psychological approaches against alternative treatments or usual care, involve both adults and adolescents, and collect measures of pain intensity, pain disability and psychological distress until at least 12 months post-treatment.

PLAIN LANGUAGE SUMMARY

What are the benefits and risks of psychological therapies for adults and young people over 12 years old with painful temporomandibular disorders (TMDs)?

Key messages

The overall results are mixed, but indicate that psychological therapies may be a useful approach for painful TMD as there is some limited evidence that they can reduce the pain. Our review suggests that they may do this at least as well as other available treatments. Any negative effects of psychological therapies are unclear, and more research is needed before we can know whether they provide a noticeable benefit while causing no or few problems.

What is the condition?

Temporomandibular disorders (TMDs) are conditions that affect the jaw joint and the muscles that move it. They are often associated with pain that lasts more than 3 months (known as chronic pain). Other symptoms include limited mouth opening, and jaw clicking and locking. All symptoms can interfere with quality of life and mood.

What did we want to know?

We wanted to find out how effective psychological therapies are for adults and young people over the age of 12 years who have painful TMD that has lasted at least 3 months.

What did we do?

We searched databases of medical and dental journals and research studies. We only selected studies known as 'randomised controlled trials (RCTs)'. In this type of study, participants are allocated to groups randomly. One group receives the intervention and the other receives a different treatment or no treatment at all. RCTs aim to reduce the risk of introducing bias in clinical studies.

We looked for reports of RCTs of psychological therapies compared to different treatments or no treatment in people over 12 years of age. Most of the reports we found compared psychological therapy to medication or the use of a special mouthguard.

We chose to focus on three measures of success. These were reduction in pain intensity, interference with activities caused by pain ('pain disability'), and psychological distress. We looked for details of these measures immediately after treatment and a few months later. We also looked for information on any 'adverse effects' (negative side effects of the treatments).

We used standard Cochrane methods to decide which studies to include, collect the key information from the studies, judge whether or not the studies were biased in any way, and judge how certain we can be about the results.

What did we find?

Overall we found 22 relevant studies. Most of the studies reported on one particular form of psychological therapy called cognitive behaviour therapy (CBT). We did not have enough information to draw any conclusions about any other psychological therapies.

The results told us that CBT was no different to other treatments (e.g. oral splints, medicine) or usual care/no treatment in reducing the intensity of the TMD pain by the end of treatment. There was some evidence that people who had CBT might have slightly less pain a few months after treatment.

There was some evidence that CBT might be better than other treatments for reducing psychological distress both at the end of treatment and a few months later. This was not seen in the one study that compared CBT against usual care.

In terms of how much pain interfered with activities, there was no evidence that there was any difference between CBT and other treatments.

There was too little information to be sure about whether psychological treatments cause adverse effects (problems caused by treatment such as feeling unwell or worse pain or unexpected effects). Only six of the 22 studies measured what adverse effects participants experienced. In these six studies, adverse effects associated with psychological treatment seemed to be minor in general and to occur less often than in alternative treatment groups.

What are the limitations of the evidence?

We have little confidence in the evidence because many of the studies had design limitations. There was also variation in the length of treatment and in how it was delivered. This means that we need to be cautious in interpreting the results that we found and they may not be reliable.

How up to date is the evidence?

We searched for studies up to 21 October 2021.

SUMMARY OF FINDINGS

Summary of findings 1. CBT versus alternative active intervention for painful TMD

CBT compared with alternative treatment for painful TMD

Population: people with painful TMD

Settings: any primary, secondary or tertiary care setting

Intervention: CBT

Comparison: alternative treatment

Outcomes	Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
Pain intensity at treatment completion Pain intensity measured by multiple scales including CPI, BPI, McGill Pain Questionnaire, VAS or numerical rating scales. Higher scores indicate higher pain intensity.	Mean pain intensity in the CBT group was 0.03 SDs higher (0.21 lower to 0.28 higher)	509 (5 RCTs)	⊕⊕⊖⊖ Low[a]	
Pain intensity at follow-up (6-12 months) Pain intensity measured by multiple scales including CPI, BPI, McGill Pain Questionnaire, MPI, VAS or numerical rating scales. Higher scores indicate higher pain intensity.	Mean pain intensity in the CBT group was 0.29 SDs lower (0.50 lower to 0.08 lower)	475 (5 RCTs)	⊕⊕⊖⊖ Low[a]	
Disability caused by pain at treatment completion Measured by multiple scales including GCPS, RMDQ, PSEQ, OHIP, PDI, numerical rating scales. Higher scores indicate higher disability.	Mean disability in the CBT group was 0.15 SDs lower (0.40 lower to 0.10 higher)	245 (3 RCTs)	⊕⊕⊖⊖ Low[a]	
Disability caused by pain at follow-up Measured by multiple scales including GCPS, RMDQ, PSEQ, OHIP, PDI, numerical rating scales.	Mean disability in the CBT group was 0.15 SDs lower (0.42 lower to 0.12 higher)	245 (3 RCTs)	⊕⊕⊖⊖ Low[a]	

Higher scores indicate higher disability.			
Adverse events	3 studies reported minor adverse events in the control group; 1 study reported minor adverse events in psychological therapy group; 1 study reported that there were no adverse events	(5 RCTs)	⊕⊖⊖⊖ Very low[b]
Psychological distress at treatment completion Measured by multiple scales including PHQ-9, CES-D, BDI, SF-36, SCL-90 Higher scores indicate higher distress.	Mean psychological distress in the CBT group was 0.32 SDs lower (0.50 lower to 0.15 lower)	553 (6 RCTs)	⊕⊕⊖⊖ Low[a]
Psychological distress at follow-up Measured by multiple scales including PHQ-9, CES-D, BDI, SF-36, SCL-90 Higher scores indicate higher distress.	Mean psychological distress in the CBT group was 0.32 SDs lower (0.51 lower to 0.13 lower)	516 (6 RCTs)	⊕⊕⊖⊖ Low[a]

BDI: Beck Depression Inventory; BPI: Brief Pain Inventory; CBT: cognitive behaviour therapy; CES-D: Centre for Epidemiological Studies in Depression; CPI: Characteristic Pain Intensity; GCPS: Graded Chronic Pain Scale; OHIP: Oral Health Impact Scale; MPI: Multidimensional Pain Inventory; PDI: Pain Disability Index; PHQ-9: Patient Health Questionnaire; PSEQ: Pain Self-Efficacy Questionnaire; RCT: randomised controlled trial; RMDQ: Roland-Morris Disability Questionnaire; RMPQ: Roland-Morris Disability Questionnaire; SD: standard deviation; SF-36: Short Form-36; SCL-90: Symptom Checklist 90 Revised; TMD: temporomandibular disorder; VAS: visual analogue scale

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded by two levels for risk of bias and imprecision.
[b]Downgraded by three levels for inconsistency, risk of bias and imprecision.

Summary of findings 2. CBT versus control for painful TMD

CBT compared with usual care or no-treatment control for painful TMD

Population: people with painful TMD

Settings: any primary, secondary or tertiary care setting

Intervention: CBT

Comparison: usual care, waiting list or no treatment

Outcomes	Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
Pain intensity at treatment completion Measured by multiple scales including CPI, BPI, McGill Pain Questionnaire, VAS or numerical rating scales Higher scores indicate higher pain intensity.	Mean pain intensity in the CBT group was 0.09 SDs lower (0.30 to 0.12 lower)	577 (6 RCTs)	⊕⊕⊖⊖ Low[a]	
Pain intensity at follow-up (12 months) Measured by multiple scales including CPI, BPI, McGill Pain Questionnaire, VAS or numerical rating scales Higher scores indicate higher pain intensity.	Mean pain intensity in the CBT group was 0.30 SDs lower (0.51 to 0.09 lower)	639 (6 RCTs)	⊕⊕⊖⊖ Low[a]	
Pain disability at treatment completion Pain disability or interference measured by multiple scales including GCPS, RMDQ, PSEQ, OHIP, PDI, numerical rating scales. Higher scores indicate higher disability.	Mean disability in the CBT group was 0.02 SDs higher (0.21 lower to 0.24 higher)	315 (3 RCTs)	⊕⊕⊖⊖ Low[a]	
Pain disability at follow-up Pain disability or pain interference measured by multiple scales including GCPS, RMDQ, PSEQ, OHIP, PDI, numerical rating scales. Higher scores indicate higher disability.	Mean disability in the CBT group was 0.01 SDs higher (0.61 lower to 0.64 higher)	240 (2 RCTs)	⊕⊕⊖⊖ Low[a]	
Adverse events	Only 1 study reported adverse events as an outcome: it found worsening symptoms in 13 people treated with an oral splint (as part of standard treatment) and 4 people treated with CBT.	101 (1 RCT)	⊕⊖⊖⊖ Very low[b]	
Psychological distress at treatment completion Measured by multiple scales including PHQ-9, CES-D, BDI, SF-36, SCL-90.	MD 2.36, 95% CI -1.17 to 3.89	101 (1 RCT)	⊕⊕⊖⊖ Low[a]	

Higher scores indicate higher distress.			
Psychological distress at follow-up Measured by multiple scales including PHQ-9, CES-D, BDI, SF-36, SCL-90 Higher scores indicate higher distress.	MD -1.02, 95% CI -4.02 to 1.98	101 (1 RCT)	⊕⊕⊖⊖ Low[a]

BDI: Beck Depression Inventory; BPI: Brief Pain Inventory; CBT: cognitive behaviour therapy; CES-D: Centre for Epidemiological Studies in Depression; CPI: Characteristic Pain Intensity; GCPS: Graded Chronic Pain Scale; OHIP: Oral Health Impact Scale; PDI: Pain Disability Index; PHQ-9: Patient Health Questionnaire; PSEQ: Pain Self-Efficacy Questionnaire; RCT: randomised controlled trial; RMDQ: Roland-Morris Disability Questionnaire; SF-36: Short Form-36; SCL-90: Symptom Checklist 90 Revised; SD: standard deviation; SMD: standardised mean difference; TMD: temporomandibular disorder; VAS: visual analogue scale

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded by two levels for risk of bias and imprecision or inconsistency.
[b]Downgraded by three levels for inconsistency, risk of bias and imprecision.

BACKGROUND

Description of the condition

Temporomandibular disorders (TMDs) are a group of musculoskeletal conditions affecting the muscles of mastication, temporomandibular joints, and associated tissues (Durham 2015; Greene 2010). They are frequently painful and are the second-most common cause of pain after low back pain (NIDCR 2019), affecting 5% to 12% of people internationally (Sharma 2018). The term, TMD, covers a range of diagnostic subtypes, including the most common: muscle-related pain (myalgia, local myalgia, myofascial pain, myofascial pain with referral), joint or disc-related problems (arthralgia and varying types of disc displacements), and headache attributed to TMD (Schiffman 2014). Clinical signs and symptoms of TMD occur in and around the jaw area, which may also spread throughout the face. Painful TMD may include pain originating from the muscles, articular disc, or jaw joint, and may involve a range of signs and symptoms, including joint sounds, headache, local or diffuse pain, and restricted mobility of the temporomandibular joint (Beecroft 2019).

The first onset incidence of TMD in adults is estimated at between 4% and 19% per annum (Slade 2013), and TMDs are estimated to be 1.5 to 2 times more common in women compared to men (Sharma 2018). Nearly half of people who experience pain continue to do so beyond 6 months (Slade 2016). TMD may be diagnosed based on an examination and history of clinical symptoms or may follow more operationalised diagnostic systems that have been developed, such as the Diagnostic Criteria for TMD (DC/TMD) (Schiffman 2014) or Research Diagnostic Criteria for TMD (RDC/TMD) (Dworkin 1992). TMD are commonly managed by a wide range of clinicians, including general dental and medical practitioners, and medical and dental specialists in secondary care.

TMDs are associated with symptoms including pain, limited mouth opening, and jaw clicking and locking; they are known to have significant impacts on quality of life and daily activities (Durham 2010), including particular challenges for communication, mastication, and intimacy (Durham 2007; Durham 2010). They are biopsychosocial in nature (Dworkin 1994; Ohrbach 2018), i.e. influenced by continual interaction of biological, psychological, and social elements. TMDs share characteristics with other persistent pain conditions, including distress and interference in everyday tasks and meaningful activities. Indeed, they are often comorbid with other pain conditions (Schiffman 2014). From a psychological perspective, pain, limitations to functional activities and impact on mood are of primary concern, and the psychological interventions applied are unlikely to differ substantially according to subtype of TMD.

Recommended treatment for people with TMD aged 12 or above in the UK is summarised by a National Institute for Health and Care Excellence (NICE) Clinical Knowledge Summary (NICE 2016). The guidelines recommend giving information and reassurance about the normal non-progressive nature of the condition. Recommended advice to people at an early stage of TMD is to: restrict eating to a soft-food diet; identify and address signs of stress; avoid parafunctional activities such as bracing, clenching, and wide yawning; relax the jaw; and manage the pain with heat, ice, and over-the-counter medications. The guidelines also suggest that for people with TMD who have a habit of clenching or grinding their teeth, an oral appliance (also referred to as an oral splint) may be appropriate. Dentists frequently use oral splints as a first-line treatment (Aggarwal 2012). Once pain has lasted beyond 3 months, it is defined as chronic (or persistent) (Treede 2015). At this stage, pain is likely to be maintained by an interaction of biopsychosocial factors regardless of the original cause of the pain (Loeser 1999); psychological treatments are therefore likely to be helpful at this stage.

The NICE 2016 Clinical Knowledge Summary recommends referral for psychological input if the person with TMD has co-existing anxiety or high levels of distress (NICE 2016). However, psychological treatment for management of pain does not only focus on reducing anxiety and depression. It can also be part of a broader management strategy that has alleviation of pain and disability as key treatment outcomes (Williams 2012). Psychological treatment will often target improved self-management as a means to achieve reductions in pain and disability. Typically, interventions are likely to be individual or group-based behavioural or cognitive-behavioural therapies delivered over a fixed period of between 4 and 12 sessions, which research studies evaluate against attention control or usual care. Interventions may include a wide variety and number of components, all of which have been designed to reduce pain, reduce the disability and distress associated with pain, or to increase adaptive behaviours in the presence of pain, using psychological principles.

Description of the intervention

Psychological therapies refer to a broad range of interventions, which can be delivered individually or in group settings. They are informed by theories of human behaviour (Williams 2012), and usually involve a combination of education and development of new cognitive and behavioural skills, which are introduced to patients and then practised in real-life settings. Psychological therapies are often delivered as part of a multidisciplinary approach alongside other non-pharmacological treatments including physiotherapy (Paço 2016), oral splints (Singh 2017), routine self-management support (Palmer 2022; Story 2016), and also alongside pharmacological treatments, where these are indicated (Mujakperuo 2010). Evidence for the effectiveness of psychological therapies is weak or equivocal at present, with too few studies to draw definitive conclusions.

Psychological therapies for TMD commonly involve behavioural interventions (Fordyce 1968), alone or in conjunction with cognitive interventions (Turk 1983); a purely cognitive approach is rarely used. Cognitive behaviour therapy (CBT) is used most often (Turk 1983), and has some evidence of effectiveness (Randhawa 2016). Cognitive approaches aim to help people with TMD to evaluate their thoughts for accuracy and helpfulness, and to provide strategies for recognising and changing, or responding differently to, patterns of thinking or core beliefs that may be contributing to pain or distress. Behavioural approaches to pain management focus on changing what the person does; for example, teaching biofeedback or relaxation techniques, or using positive reinforcement to reduce behaviours that might exacerbate pain. Biofeedback involves relaxation alongside physiological feedback through an electronic device so that people are able to monitor how relaxed they are physiologically. We do not consider biofeedback, as a stand-alone intervention, to represent a psychological therapy. We will, however, include studies that have biofeedback as a behavioural component alongside other psychological interventions.

Numerous psychological therapies that could potentially be helpful in TMD have been applied within more general persistent pain settings (Barker 2019), for example, 'third-wave' cognitive therapies, which focus on the context rather than the content of thoughts. Acceptance and commitment therapy (ACT) is one such 'third-wave' therapy, which aims to change the way that people relate to their thoughts, sensations, and other internal experiences rather than trying to influence the experiences themselves (Dahl 2004; Hayes 1999); people are encouraged to pursue life goals that are important and meaningful to them, even if doing so involves experiencing difficult and painful feelings. Compassion-focused therapy also aims to help people to relate differently to their internal experiences, using insights from evolutionary psychology to explain to people why they might have thoughts and engage in behaviours that could be unhelpful and difficult to understand, and then helping them to adopt a kinder, gentler, and therefore more helpful attitude towards their difficulties. This process then helps to interrupt habitual patterns of resistance that might otherwise intensify pain (Gooding 2020; Penlington 2019a). Cognitive functional therapy integrates methods associated with psychology and physiotherapy to develop a personalised understanding of factors that may be contributing to pain, leading to an evolving and personalised plan to reduce and change these factors (O'Sullivan 2012). Mindfulness is a method of staying with, or returning to, present-moment experience that can also lead to changes in the habitual ways that people respond to difficulty such as pain or distress. Mindfulness will be included within this Cochrane Review as it is based on a psychology of human minds and how they work, and has been widely applied in pain management settings (Kabat-Zinn 1982).

Frequently, psychological therapies are delivered as part of a broader biopsychosocial intervention by a multidisciplinary team of psychologists, physiotherapists, doctors, dentists, and other health professionals with specific expertise in the management of pain. The psychological components are delivered by specialist psychologists or other staff who have been trained and are supervised by psychologists. Psychological therapies for adults may also involve information or specific sessions targeted to family, significant others or carers of the individual with TMD. For adolescents under the age of 18, a systemic approach involving family would usually be an important component of psychological treatment.

Psychological therapies have a range of levels of intensity and formats for delivery. Increasingly these are delivered within a stepped care model which might, for example, include pure self-help (step 1), guided self-help or group therapy often delivered by a psychological well-being practitioner or nurse (step 2), brief individual therapy (step 3), or more intensive individual therapy of longer duration (step 4) (Bower 2005). There is some early evidence that this approach can usefully be applied to psychological therapies for pain management (Bell 2020). There is some evidence in the field of TMD for matching psychological interventions to pain characteristics that might suggest the utility of a stepped care model. Psychological interventions may be more successful and require less intensive input for people who report pain that is less disabling (Dworkin 2002a), and of shorter duration (Gatchel 2006; Gatchel 2014), compared with longer-standing and more disabling pain. The differential need for treatment according to individual factors, including disability, is established in general pain management services by initiatives such as the STarT Back trial (Hill 2011).

How the intervention might work

An important aim of psychological therapies for TMD is to support self-management. Self-management is recognised in national and international guidelines as the first-line treatment for TMD (De Leeuw 2008; Durham 2015; Greene 2010). Self-management refers to a person's use of a range of strategies to enable them to live well with pain, minimising pain where possible while also minimising its impact on life. Although it is considered to be an important aspect of living with pain, successful self-management can be difficult to achieve. An instinctive response to pain is to try to fight or avoid it. When pain persists in the absence of a treatable cause or despite optimal medical management, these automatic responses can cause distress and may maintain and even increase the intensity of pain. Psychological therapies support self-management by encouraging behaviours that are helpful and reducing responses that are potentially harmful, including helping to overcome barriers to effective engagement in self-management, where necessary (Williams 2012). Targets of such therapies will depend on the theory on which they are based, but may include reducing anxiety or depression, modifying stress reactivity or reducing habitual behaviours, introducing effective coping strategies, increasing confidence and ability to engage in rewarding and meaningful activities, reframing the meaning of pain, or redirecting focus away from pain and towards valued life goals.

Why it is important to do this review

TMDs are common (painful) problems that have a significant impact on individuals and society (Sharma 2018). Clinically, a wide range of interventions are used to treat TMDs and there is a need for accurate scientific evidence to direct the use of such interventions. TMD can present with a wide range of severity and complexity, and different treatment approaches may be appropriate for different presentations. Clinical guidelines highlight the importance of self-management from an early stage and alongside other treatment (Greene 2010). Support for self-management is an approach that is psychological in nature, although this is not made explicit in the current literature relating to TMD. The self-management support that is currently provided as part of routine care therefore lacks an evidence base, is highly variable, and is often delivered without psychological training or support.

Dentists, who are frequently the first point of contact for people with painful TMD, are often not confident about this aspect of management, partly due to a reported/perceived lack of training in TMD and persistent pain (Durham 2007). They also face organisational and training barriers to the delivery of appropriate education and support for self-management (Peters 2015), and tend to prescribe an oral appliance and/or refer to dental specialists as a first line of treatment (Aggarwal 2012). Few providers of psychological therapies are integrated with, or have expertise in, orofacial pain, and where referrals are made to community psychology services or pain clinics, waiting times are often long. Potentially, therefore, current treatment provision may be suboptimal for people with TMD. There is some evidence that early psychological therapy targeted towards people with higher reported disability and distress associated with TMD can improve long-term outcomes and reduce the chances of the pain persisting

beyond a year (Gatchel 2014). More literature is available for psychological interventions for persistent pain in TMD at a higher level of intensity, usually for people with longer durations of pain, where weak evidence for psychological treatments is reported alongside the need for more high-quality trials. The most recent review of this literature included primary literature published up to 2014 (Randhawa 2016). There is, therefore, a need for an updated comprehensive systematic review of psychological therapies for painful TMD to assist providers and commissioners in the planning and development of services to best meet the needs of people with TMD according to current scientific evidence.

Clinical practice guidelines for TMD start at age 12 years (NICE 2016). Although incidence of TMD is lower for adolescents than adults, presentations during adolescence do occur. Incidence of new-onset TMD is known to increase between the ages of 12 and 19 years. A 3-year longitudinal study in Sweden found that 11.4% of adolescents reported TMD pain on at least one occasion, though the proportion with chronic pain was less than 1% (Nilsson 2007). There is currently no available review of psychological therapies for TMD in adolescents, therefore there is a need to also consider evidence that may be available for psychological therapies in this population.

OBJECTIVES

To assess the effects of psychological therapies in people (aged 12 years and over) with painful TMD lasting 3 months or longer.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) of any psychological therapy (e.g. cognitive behaviour therapy (CBT), behaviour therapy (BT), acceptance and commitment therapy (ACT), mindfulness) for the management of painful TMD. We included cross-over trials if the effects of each arm could be evaluated independently. Studies needed to be based on recognisable psychological theory, as judged by the review authors, and delivered by qualified psychologists or staff trained and supervised in the treatment approach specified.

Types of participants

Eligible participants were adults and adolescents aged 12 years or older, with pain lasting 3 months or longer since initial onset of TMD diagnosed by any method. We noted exclusion criteria and recorded physical and psychological comorbidities and use of medications. We recorded whether diagnosis was made by formalised criteria including DC/TMD, RDC/TMD, or other formal method, or whether this was not stated. We included studies of interventions directed towards a mixture of pain conditions so long as information about TMD was reported separately, or if the entire sample was reported to consist of 80% or more participants with TMD.

Types of interventions

Interventions

We included any psychological intervention for the management of TMD against any control condition. We defined psychological treatments as any interventions based on any widely accepted psychological theory and delivered by psychologists or staff with appropriate behavioural healthcare training. We included mixed intervention studies if we considered at least 50% of the treatment content to be psychological in nature. We excluded studies of treatment packages that include interventions, such as oral splints or medication, where it was not possible to independently evaluate the effects of the psychological component of the intervention.

We included interventions of any format and length that met our inclusion criteria.

Comparisons

We considered psychological interventions, i.e. CBT, BT or other psychological therapy, that were compared to an alternative treatment (such as medication or oral splints) or a control condition, such as usual care (as defined by trial authors), attention control (such as a support group that contained no active treatment but offered a similar amount of face-to-face contact as the active intervention), waiting-list control, or no treatment. We also considered studies that evaluated one psychological intervention against another.

Types of outcome measures

Primary outcomes

- Pain intensity, e.g. Characteristic Pain Intensity (CPI) (Von Korff 1992), single visual analogue scale (VAS) or numerical rating scales of pain (NRS), or quantitative measures based on pain descriptors such as the McGill Pain Questionnaire (MPQ) (Melzack 1975)
- Disability caused by pain (pain impact), e.g. Graded Chronic Pain Scale (GCPS) (Von Korff 1992), Roland-Morris Disability Questionnaire (RMDQ) (Roland 2000), Oral Health Impact Scale (Slade 1994) or Pain Self-Efficacy Questionnaire (PSEQ) (Nicholas 2007)
- Adverse events

Secondary outcomes

- Psychological distress, e.g. Patient Health Questionnaire PHQ-4 (Kroenke 2009), PHQ-9 (Kroenke 2001), Hospital Anxiety and Depression (HAD) scale (Zigmond 1983), General Health Questionnaire GHQ-12 (Goldberg 1977), Beck Depression Inventory-II (BDI-II) (Beck 1996), Beck Anxiety Inventory (BAI) (Beck 1988), or Perceived Stress Scale (PSS) (Cohen 1983)
- Additional physical symptoms, e.g. Symptom Checklist SCL-90-R (Derogatis 1983), Patient Health Questionnaire PHQ-15 (Kroenke 2002)
- Quality of life, e.g. EQ-5D-5L (Oppe 2014)

These measures are self-reported patient questionnaires. We planned to report outcomes regardless of whether these were self-reported or observer-rated; in practice, all included studies used self-reported primary outcome measures. Where a study included more than one measure for a domain, we selected the measure that we judged most appropriate for that outcome, considering frequency of use of the measure in the field and reported reliability of the measure. Where follow-up data from a study were provided at more than one point in time, we reported data for the longest follow-up time available.

Search methods for identification of studies

Electronic searches

Cochrane Oral Health's Information Specialist conducted systematic searches in the following databases for RCTs and controlled clinical trials. There were no language, publication year or publication status restrictions.

- Cochrane Oral Health's Trials Register (searched 21 October 2021) (Appendix 1)
- Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Register of Studies (searched 21 October 2021) (Appendix 2)
- MEDLINE Ovid (1946 to 21 October 2021) (Appendix 3)
- Embase Ovid (1980 to 21 October 2021) (Appendix 4)
- PsycINFO Ovid (1806 to 21 October 2021) (Appendix 5)
- Trip database (www.tripdatabase.com/) (searched 21 October 2021) (Appendix 6)

The subject strategies for databases were modelled on the search strategy designed for MEDLINE Ovid in Appendix 3. Where appropriate, this was combined with subject strategy adaptations of the highly sensitive search strategy designed by Cochrane for identifying RCTs and controlled clinical trials (as described in the *Cochrane Handbook for Systematic Reviews of Interventions* Box 6.4.c (Lefebvre 2020)).

Searching other resources

Cochrane Oral Health's Information Specialist searched for grey literature in the following databases.

- Web of Science Conference Proceedings (1990 to 21 October 2021) (Appendix 7)
- Proquest Dissertations and Theses Global (1861 to 21 October 2021) (Appendix 8)
- OpenGrey (www.opengrey.eu/) (searched 21 October 2021) (Appendix 9)

The following trials registries were also searched.

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (clinicaltrials.gov/) (see Appendix 10)
- World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch) (see Appendix 11)

We searched reference lists of included studies and review articles of psychological therapies for orofacial pain in general, and TMD specifically. We checked to ensure that none of the included studies have been retracted due to error or fraud. We did not perform a separate search for adverse effects of interventions. We considered adverse events described in included studies only.

Data collection and analysis

Selection of studies

Our strategy was to include RCTs, including cross-over trials where the effects of each arm could be evaluated independently. Studies were of any psychological intervention for TMD. We designed the search to be sensitive and include controlled clinical trials, which we then filtered out early in the selection process if not randomised.

Five review authors (CP, CB, GT, AAO, PW) screened titles and abstracts of retrieved studies, and retained those that fitted the inclusion criteria or were not obviously excluded by the criteria. We obtained full-text copies and at least two of three review authors (CP, CB, GT) independently judged whether each study fulfilled the inclusion criteria. We resolved differences in opinion by discussion, initially between both review authors, and if necessary in consultation with a third review author (RO, JD, or PW). We used the following criteria for selection of studies.

- Is it a RCT?
- Does at least one arm of the trial involve primarily psychological therapy?
- Is the primary aim to reduce pain or to reduce disability associated with pain?
- Does the study refer to young persons or adults aged 12 years or older with a presenting problem of painful TMD?

Data extraction and management

We developed a standardised proforma for data extraction and piloted it on a sample of studies for clarity and completeness. We reported outcomes where available immediately postintervention and at long-term follow-up. The first review author (CP) and at least one other review author (CB or GT) independently extracted data for all included studies using the standardised proforma. Discrepancies were resolved by discussion and referred to a third review author (RO, JD, or PW) in cases where we could not reach agreement. Relevant studies were translated if not written in English. We included multiple reports of the same study when these were available and attempted to clarify with study authors where this was not clear. We recorded relevant information about the characteristics and findings from all included studies, using a proforma to record:

- basic study characteristics, such as study title and type;
- inclusion and exclusion criteria;
- participant characteristics and demographic details;
- study methods including study design, sampling methods, sample size, method of random sequence generation, and any attempt at blinding;
- intervention details, such as type, content, home practice expectations, provider, delivery format, and number, length and frequency of sessions;
- outcome data, such as outcome measure type, tool, units, and frequency and timing of outcome measurement; any outcomes not prespecified; adverse events;
- number of participants randomised and analysed;
- number of withdrawals, exclusions, loss to follow-up;
- data analysis method, attrition, and dispersion/precision;
- source of funding;
- ethical approval and consent.

Assessment of risk of bias in included studies

We applied the Cochrane RoB 1 tool to included studies (Higgins 2017). Three review authors (CP, CB, GT) independently assessed each included study for any risk of bias in sequence generation, allocation concealment, blinding of outcome assessors, incomplete outcome data, selective reporting of outcomes, and other issues. Blinding of participants and staff

for this kind of trial is not possible, since people know what intervention they have delivered or attended. The review authors assessed the risk of bias for each study as either low, unclear, or high; they resolved discrepancies by discussion between themselves. We illustrated risk of bias ratings with quotes and information from the primary research papers in each domain.

Measures of treatment effect

We reported data about measures of treatment effect immediately after treatment and at follow-up. We had planned to calculate the risk ratio (RR) and corresponding 95% confidence interval (95% CI) for any dichotomous outcomes, but none of the studies reported dichotomous outcomes. We calculated the mean difference (MD) and corresponding 95% CI for continuous outcomes that had been measured using the same units, and standardised mean differences (SMD) with corresponding 95% CI for continuous outcomes where different scales had been used to evaluate the same outcome. We applied criteria specified by Cohen 1983 for reporting effect sizes: 0.2 represents a small effect, 0.5 a moderate effect, and 0.8 a large effect. For the primary outcome of pain, we reported whether or not a clinically meaningful reduction in pain was achieved for each study. We did this by calculating within-group differences from baseline to treatment completion and to follow-up and comparing these to estimates of clinically-meaningful pain reduction, representing approximately 30% from baseline, as described in previous reviews of pain outcome measures (Al-Baghdadi 2014; Dworkin 2005; Farrar 2001; Smith 2020).

Unit of analysis issues

Cluster-randomised trials

We did not include any cluster-randomised trials. We had planned to consider data from any cluster-randomised trials at the same level as the allocation, using a summary of data from each cluster as the primary data and considering the sample size to be the number of clusters and proceed as if the trial were individually randomised, following guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019a).

Cross-over trials

We did not find data from cross-over trials. Our plan was to include data from cross-over trials separately for each phase of the trial if results were reported before and after the cross-over, and otherwise to report outcomes narratively.

Studies with multiple treatment groups

In studies which included more than one treatment arm defined as psychological therapy, we included both in the analyses. In order to avoid double counting of participants in the alternative or control groups, we split the relevant treatment alternatives into two halves and considered each intervention group against each half of the alternative treatment or control group.

Dealing with missing data

We extracted data on the basis of intention-to-treat. We contacted study authors to ask for missing data such as standard deviations (SDs) if the studies were less than 10 years old. In instances where we were unable to access this information, we described the studies as part of a narrative review only.

Assessment of heterogeneity

The nature of the interventions is such that a high degree of both clinical and methodological heterogeneity would be expected. We were not able to separately analyse interventions based on clinical characteristics. We therefore grouped studies together and described clinical characteristics of studies alongside the meta-analysis in order to provide a context for the results. For studies that we combined in meta-analyses, we assessed heterogeneity of treatment effects by visual inspection of forest plots and by using the Chi^2 test (with a significance level at $P < 0.10$) and the I^2 statistic. We based our interpretation of the I^2 results on that suggested by Higgins 2019b: 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; and 75% to 100% may represent very substantial ('considerable') heterogeneity.

Assessment of reporting biases

We searched trial registries and contacted authors of published studies included in the review to ask if they were aware of unpublished research that might be relevant to the review, in order to reduce potential publication bias. There were insufficient studies included in the meta-analyses to conduct funnel plot analyses.

Data synthesis

We combined data where we identified more than one study reporting an outcome. We did this regardless of statistical heterogeneity (as measured by the I^2 statistic) and made a note of statistical heterogeneity to put the results in context. We inputted data into Review Manager 5 (Review Manager 2020), and we conducted separate analyses at immediate post-treatment and longest available follow-up, using a random-effects model. We recorded the effect of psychological therapies on pain, disability and psychological distress. We planned to also do so for the outcomes of additional physical symptoms and quality of life; however we did not synthesise data for the latter two outcomes due to insufficient primary studies reporting on these outcomes.

Subgroup analysis and investigation of heterogeneity

If sufficient data were available, we planned to conduct subgroup analyses by age (adolescent versus adult), disability (low versus high) and time since TMD onset (> 3 months and ≤ 12 months versus ≥ 12 months). We defined 'high disability' as high risk of poor outcome or high severity where the rationale was explained and based on a standardised protocol in the original paper. This type of stratification in TMD studies has typically used scores based on the Graded Chronic Pain Scale (Von Korff 1992), or the Multidimensional Pain Inventory (Okifuji 1999). We planned to consider studies of participants aged 18 years and over against those whose participants were aged 12 to 17 years; data from studies is often restricted to adults, although the onset of TMD frequently occurs during adolescence (Christidis 2019). Where we were unable to combine studies, we reported findings narratively.

Sensitivity analysis

We performed a sensitivity analysis by separately reporting data from studies in which diagnosis was based on established reference standard diagnostic criteria, for example, RDC/TMD (Dworkin 1992), or DC/TMD guidelines (Schiffman 2014).

Summary of findings and assessment of the certainty of the evidence

We used the GRADE approach to assess the certainty of the evidence related to all outcomes listed in the types of outcome measures section above (Schünemann 2017). Using GRADEpro GDT (GRADEpro GDT), two review authors (CP, JD) assessed the certainty of the evidence as 'high', 'moderate', 'low', or 'very low' depending on the presence and extent of five factors: risk of bias, inconsistency of effect, indirectness, imprecision, and publication bias. We prepared two summary of findings tables for CBT comparisons. Data for other psychological approaches, including behavioural therapy, were insufficient to be collated in any meaningful way. We reported outcomes at treatment completion and at the longest available follow-up. For each comparison, we reported data on pain, disability, adverse events, and psychological distress, where available. We noted the total number of sessions with an appropriately trained professional and the number of weeks of active psychological treatment where this information was reported.

RESULTS

Description of studies

Results of the search

The study flow diagram is shown in Figure 1. Our searches found 2822 records, which we imported for screening. We identified one additional reference through reference lists of relevant studies. After removing duplicates, we had 1785 records. We rejected 1717 records from a screen of titles and abstracts. We read the full text of 68 papers. We rejected 10 of these because they were not RCTs; five were relevant ongoing studies (see Characteristics of ongoing studies), and we excluded 20 with reasons presented in Characteristics of excluded studies. This left 22 studies, described in 33 separate papers, for inclusion.

Figure 1. Study flow diagram

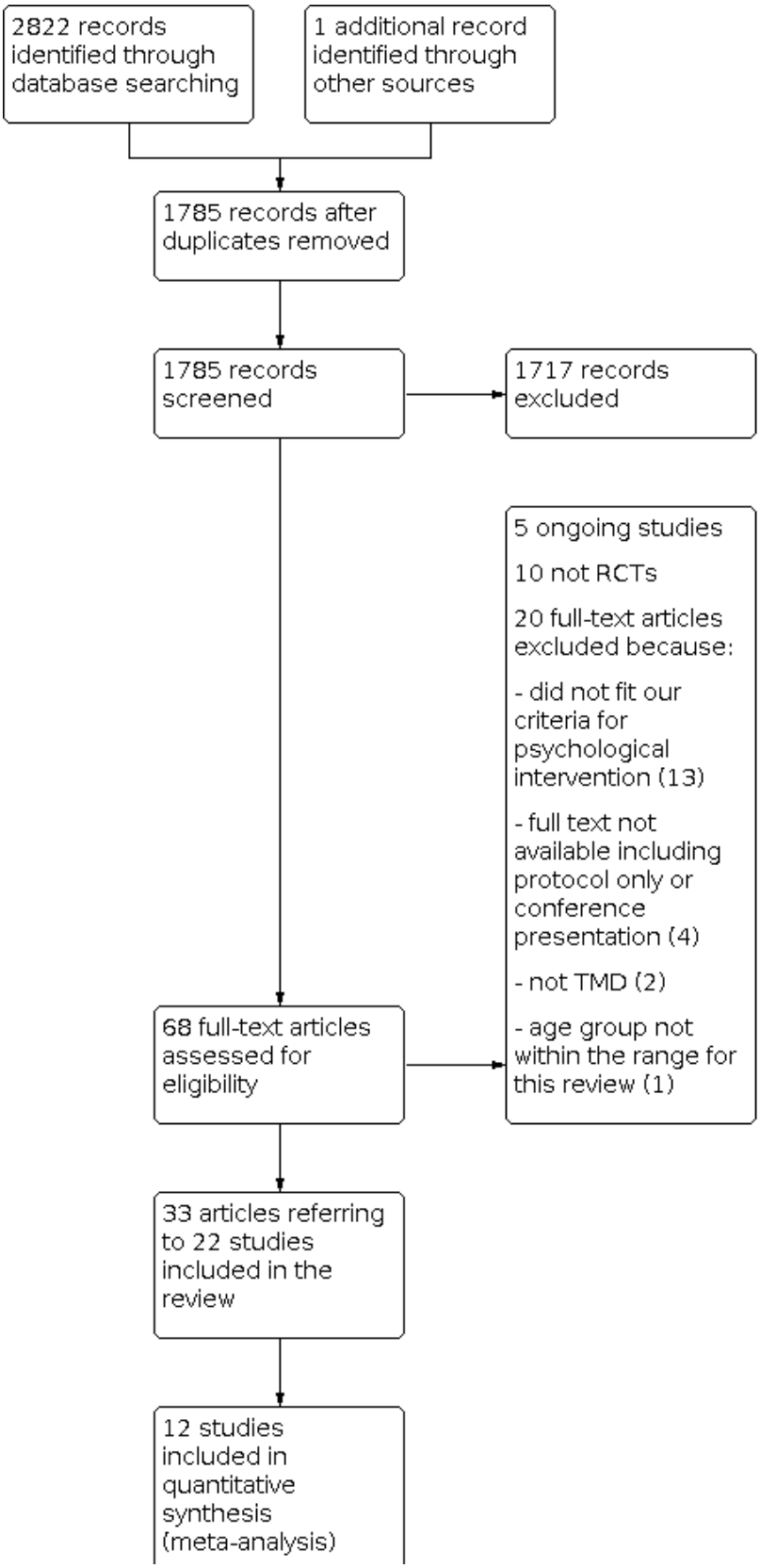
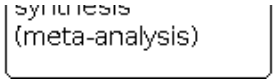


Figure 1. (Continued)



Included studies

We included 33 papers in this review, which described 22 RCTs with a total of 2001 participants (ranging from 24 to 191 per trial). The studies were clinically varied, with different numbers and durations of treatment sessions, models of treatment, home practice expectations, inclusion criteria, and outcomes (see Characteristics of included studies).

Design

Twenty-one RCTs were parallel arm in design; one study was a cross-over trial but functioned as a parallel study in this review as we used first-period data only (Wahlund 2015). Eight studies were multi-arm trials: five with 3 arms (Lupton 1968; Stam 1984; Turk 1993; Turner 2011; Wahlund 2003) and three with 4 arms (Calderon 2011; Mishra 2000; NCT00066937). We did not use one of the arms from Wahlund 2003 (control - brief information).

Setting

All but one of the studies took place in a specialist or university clinic (Townsend 2001). Studies were conducted in the USA (Bartley 2019; Dworkin 1994; Dworkin 2002a; Dworkin 2002b; Gatchel 2006; Litt 2010; Lupton 1968; Mishra 2000; Turk 1993; Turk 1996; Townsend 2001; Turner 2006; Turner 2011), Sweden (Wahlund 2003; Wahlund 2015), Brazil (Calderon 2011), Canada (Stam 1984), Denmark (Abrahamsen 2011), Germany (Mora 2013), and Russia (Shevtsova 2020). Eleven studies were funded by the American National Institutes of Health (NIH), six were unfunded, one was funded by the American Pain Society, and four had other national or local funders.

Participants

All but two studies involved adult participants. Two studies were carried out with adolescents aged 12 to 19 years (Wahlund 2003; Wahlund 2015). These studies compared a formal relaxation programme delivered by a trained therapist versus use of an occlusal appliance. We were unable to include these studies in the data synthesis due to the format in which the outcomes were reported.

Most of the studies included a mix of people who had experienced persistent pain related to TMD for at least 6 months, and often over many years. One study specifically recruited people with recent onset of pain (within the past year) (Gatchel 2006). Two others used an algorithm to allocate participants who were deemed high or low complexity to different interventions (Dworkin 2002a; Dworkin 2002b).

Psychological interventions

The majority of the studies evaluated CBT (alone or in combination with biofeedback) (Calderon 2011; Dworkin 2002a; Dworkin 2002b; Dworkin 1994; Gatchel 2006; Litt 2010; Mishra 2000; Mora 2013; NCT00066937; Turk 1993; Turk 1996; Turner 2006; Turner 2011), with the remainder evaluating CBT and hypnosis in a single treatment package (Ferrando 2012), relaxation (Abrahamsen 2011; Stam 1984; Wahlund 2003; Wahlund 2015), hypnosis (Abrahamsen 2011; Stam 1984), habit reversal training (Townsend 2001), a 'hope-based intervention' (Bartley 2019), mindfulness (Shevtsova 2020), and education and counselling (Lupton 1968).

Comparison interventions

Alternative treatment

- Pharmacological interventions (either alone or in combination with psychological intervention) (Calderon 2011; NCT00066937; Shevtsova 2020; Turner 2011)
- Occlusal appliances (either alone or in combination with psychological intervention) (Mora 2013; Turk 1993; Wahlund 2003; Wahlund 2015)
- Self-care management (Turner 2006)
- Disease management (alone or with medication) (NCT00066937)
- Pain education (Bartley 2019)
- Non-directive counselling (Turk 1996)
- Another psychological intervention (or combination): hypnosis versus relaxation (Abrahamsen 2011; Stam 1984); CBT versus biofeedback or combination of CBT + biofeedback (Mishra 2000).

Usual care or no treatment

- Usual care (Dworkin 1994; Dworkin 2002a; Dworkin 2002b; Ferrando 2012 ; Gatchel 2006; Litt 2010; Lupton 1968)
- Waiting-list control/no treatment/placebo (Calderon 2011; Mishra 2000; Stam 1984; Townsend 2001; Turk 1993)

Outcomes

Primary outcomes

We selected one measure from each study for each of the outcomes of interest. Where a study measured a single outcome using more than one measure, we selected the measure to include based on IMMPACT recommendations for measuring chronic pain (Dworkin 2005). For pain intensity, we included pain reported on a measure that included combined numerical rating scales, such as the Characteristic Pain Intensity (CPI) (Von Korff 1992) or the Brief Pain Inventory (Tan 2004), where available. Pain intensity was reported in this way in 12 studies (Abrahamsen 2011; Dworkin 1994; Dworkin 2002a; Dworkin 2002b; Ferrando 2012; Mishra 2000; Gatchel 2006; Mora 2013; Turner 2006; Turner 2011; Wahlund 2003; Wahlund 2015). Where combined numerical rating measures were not used, we chose pain intensity rated by a single numerical rating scale (NCT00066937), a visual analogue scale (Calderon 2011) or other psychometrically validated pain measures such as the McGill Pain Questionnaire (Melzack 1975), which was reported by Turk 1996. Where none of these measures were available, we used reports of a subscale of a validated pain questionnaire, as reported by Litt 2010 and Townsend 2001.

For pain disability, we prioritised validated pain disability questionnaires including the Oral Health Impact Profile used by Calderon 2011, Pain Disability Index reported by Mora 2013, followed by validated pain interference questionnaires, which

included the Chronic Pain Self-efficacy Scale reported by Litt 2010 and the Pain Self-Efficacy Questionnaire reported by Bartley 2019. If none of these scales were reported, we used the overall category from the Graded Chronic Pain Scale as reported by Dworkin 2002a, Mishra 2000 and Turner 2006, or a subscale of a validated pain scale as reported by Turk 1996 and Ferrando 2012.

We reported adverse events in any way that was described by study authors.

We reported outcomes at the end of treatment (shortest duration 4 weeks) and longest post-treatment follow-up (12 months).

Secondary outcomes

For psychological distress, we used validated depression questionnaires: the Center for Epidemiological Studies for Depression (CES-D, Radloff 1977), reported by Bartley 2019, Mora 2013, Litt 2010; Beck Depression Inventory-II (BDI-II, Beck 1988) reported by Calderon 2011, Gatchel 2006, Turk 1996, Turner 2006, Turner 2011; or the Short-Form-36 (SF-36, Ware 1994) used by NCT00066937. Otherwise we used an anxiety scale (no studies reported anxiety in the absence of depression), or a relevant subscale of a validated instrument (Abrahamsen 2011; Dworkin 1994; Ferrando 2012).

We reported whichever measure was used to document additional physical symptoms and quality of life: screening for somatoform symptoms (Mora 2013), or relevant subscales from Profile of Mood States (POMS, McNair 1971 used by Mishra 2000) or Symptom Checklist-Revised (SCL-90-R, Derogatis 1983) reported by Dworkin 1994, Dworkin 2002a and Dworkin 2002b.

Available data

Of the studies reporting outcomes of CBT, 12 included quantitative data that could be combined (Dworkin 2002a; Dworkin 2002b; Dworkin 1994; Gatchel 2006; Litt 2010; Mishra 2000; Mora 2013; NCT00066937; Turk 1993; Turk 1996; Turner 2006; Turner 2011), and one presented data that did not include data suitable for meta-analysis (Calderon 2011). As mentioned above, one study combined CBT and hypnosis in a single package (Ferrando 2012). Of the remaining eight studies, four included data that could be quantitatively analysed (Abrahamsen 2011; Bartley 2019; Townsend 2001; Wahlund 2015), and four could not be combined (Lupton 1968; Shevtsova 2020; Stam 1984; Wahlund 2003).

Excluded studies

We excluded 20 RCTs, described in 20 separate papers after looking at the full texts (see Characteristics of excluded studies). Our reasons for exclusion were that they did not fit our criteria for psychological intervention (13 studies); participants were not diagnosed with persistent TMD (2 studies); data of participants with TMD could not be disaggregated (1 study); or there was insufficient information for inclusion as they were conference proceedings only or we could not source the full text (4 studies).

Ongoing studies

Five studies are ongoing and may be included in the update of this review if data are available by then (see Characteristics of ongoing studies).

Risk of bias in included studies

Our risk of bias judgements are shown in Figure 2. We followed the six Cochrane categories of random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other potential sources of bias.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

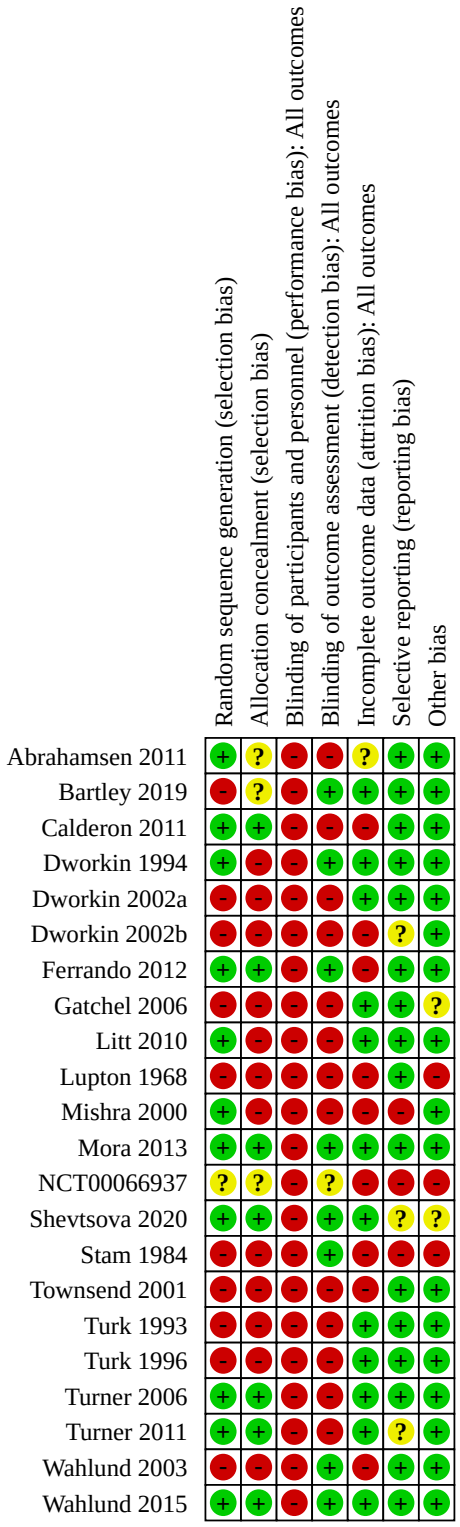


Figure 2. (Continued)

Allocation

We assessed that 11 studies provided a clear description of randomisation and were at low risk of bias for random sequence generation. One study was at unclear risk of bias, and we judged that 10 were at high risk of bias.

Only seven studies reported allocation concealment, and we assessed these as being at low risk of bias for this domain. We assessed that three studies were unclear and 12 were at high risk of bias.

Overall, we judged seven studies to be at low risk of selection bias (Calderon 2011; Ferrando 2012; Mora 2013; Shevtsova 2020; Turner 2006; Turner 2011; Wahlund 2015), two to be unclear (Abrahamsen 2011; NCT00066937), and the remaining 13 to be at high risk.

Blinding

Blinding of participants and personnel is not possible with psychological interventions since both those providing and receiving the intervention must necessarily know what they are providing or receiving.

Eight studies provided information about blinding of outcome assessors that led us to rating them as low risk of detection bias (Bartley 2019; Dworkin 1994; Ferrando 2012; Mora 2013; Shevtsova 2020; Stam 1984; Wahlund 2003; Wahlund 2015), one as unclear (NCT00066937), and the remainder at high risk of detection bias.

Incomplete outcome data

We judged 12 studies as low risk of bias for incomplete outcome data (Bartley 2019; Dworkin 1994; Dworkin 2002a; Gatchel 2006; Litt 2010; Mora 2013; Shevtsova 2020; Turk 1993; Turk 1996; Turner 2006; Turner 2011; Wahlund 2015). These studies reported rates of dropout that were low and used intention-to-treat analyses. We judged an unclear risk of bias for one study (Abrahamsen 2011), and high risk of attrition bias for the remaining nine.

Selective reporting

We based our judgement on whether all outcomes listed in the methods section were reported and whether there was a plausible rationale for including these outcomes. On this basis, we judged 16 studies to be at low risk of reporting bias, three studies to be unclear (Dworkin 2002b; Shevtsova 2020; Turner 2011), and three studies to be at high risk of reporting bias (Mishra 2000; NCT00066937; Stam 1984).

Other potential sources of bias

We judged that 17 studies had no other potential sources of bias that we could identify, two were unclear (Gatchel 2006; Shevtsova 2020), and the remaining three were at high risk of bias. Of these three, two were conducted over 30 years ago (Lupton 1968; Stam 1984), and the other was reported in a clinical trials registry but never published (NCT00066937).

Effects of interventions

See: **Summary of findings 1** CBT versus alternative active intervention for painful TMD; **Summary of findings 2** CBT versus control for painful TMD

CBT versus alternative treatment

Six studies reported results of comparisons of CBT against alternative treatments on at least one outcome that we were able to combine (Mora 2013; NCT00066937; Turk 1993; Turk 1996; Turner 2006; Turner 2011). Alternative treatments were diverse and included an intraoral appliance (Mora 2013; Turk 1993), self-care management (Turner 2006), disease management plus placebo (NCT00066937), disease management plus nortriptyline (NCT00066937), and oral contraceptive management (Turner 2011). See Summary of findings 1 for key results for this comparison.

Primary outcomes

Pain intensity

Pain intensity at treatment completion was reported by five studies of 509 participants (Mora 2013; NCT00066937; Turk 1993; Turner 2006; Turner 2011). There was no evidence of any difference between CBT and alternative treatments at treatment completion (standardised mean difference (SMD) 0.03, confidence interval (CI) -0.21 to 0.28; heterogeneity measured by I^2 = 44%; low-certainty evidence; Analysis 1.1). At longest available follow-up (between 6 and 12 months), there was a small difference in favour of CBT for pain intensity (SMD -0.29, CI -0.50 to -0.08; I^2 = 17%; 5 studies, 475 participants; low-certainty evidence; Analysis 1.2). One study presented data that could not be combined to compare CBT with an alternative treatment (Calderon 2011). Findings were inconsistent with regard to interventions and alternative treatment groups achieving at least a 30% reduction in pain intensity at treatment completion and at follow-up (Table 1).

Sensitivity analysis

We removed studies that had not used an established diagnostic method, such as the RDC/TMD to diagnose TMDs. This left only two studies that evaluated pain intensity at treatment completion (Turner 2006; Turner 2011) (SMD -0.09, 95% CI -0.33 to 0.15; I^2 = 0%; 276 participants; Analysis 1.3). Pain intensity at follow-up was reported by two studies, with data for 290 participants in total, with a SMD of -0.45 (95% CI -0.69 to -0.21; I^2 = 0%; Analysis 1.4).

Disability caused by pain

Three studies representing a total of 245 participants reported data on pain disability. Heterogeneity for this outcome was 0% at both treatment completion and follow-up. There was no evidence of any difference between CBT and alternative treatment at treatment completion (SMD -0.15, CI -0.40 to 0.10; I^2 = 0%; low-certainty evidence; Analysis 1.5) or at follow-up (SMD -0.15, CI -0.42 to 0.12; I^2 = 0%; low-certainty evidence; Analysis 1.6).

Adverse events

Adverse effects were reported by three studies. NCT00066937 reported minor adverse effects including constipation, dry mouth or sedation in 56% to 78% of participants, all of whom took nortriptyline or benztropine. Turner 2011 reported that no adverse effects were recorded in their self-management intervention and that breakthrough bleeding (47%), increased appetite or weight gain (11%), increased moodiness (11%), breast tenderness (8%), and increased acne (8%) were relatively common occurrences in those treated with a combined oral contraceptive. Mora 2013 reported that 7 out of 27 people treated with an oral splint reported worse symptoms compared with 3 out of 29 people in the biofeedback with CBT group.

Secondary outcomes

Psychological distress

Psychological distress at treatment completion was reported by six studies of 553 participants. There was evidence of a small advantage of CBT over alternative treatments on this outcome (SMD -0.32, CI -0.50 to -0.15; I^2 = 3%; low-certainty evidence; Analysis 1.7). At follow-up, including 516 participants from 6 studies, the small advantage of CBT was maintained (SMD -0.32, CI -0.51 to -0.13; I^2 = 8%; low-certainty evidence; Analysis 1.8).

Additional physical symptoms

This outcome was not measured.

Quality of life

This outcome was not measured.

CBT versus usual care or waiting list/no treatment control

We combined usual care, no-treatment control and waiting-list control, as conditions that did not include any active alternative treatments mimicked usual clinical care, and did not require usual treatment to be specifically withheld for the duration of the trial. Seven studies included data that could be combined for at least one outcome (Dworkin 2002a; Dworkin 2002b; Dworkin 1994; Gatchel 2006 Litt 2010; Mishra 2000; Turk 1993). An additional study evaluated CBT plus placebo against placebo alone but did not include data suitable for inclusion in a meta-analysis (Calderon 2011). See Summary of findings 2 for key results for this comparison.

Primary outcomes

Pain intensity

For CBT against control, six studies of 577 participants in total reported pain intensity at treatment completion (Dworkin 1994; Dworkin 2002a; Dworkin 2002b; Litt 2010; Mishra 2000; Turk 1993). At treatment completion, I^2 was 34%, and at follow-up I^2 was 38%. There was no evidence of a difference between CBT and control for pain intensity at treatment completion (SMD -0.09, CI -0.30 to 0.12; P = 0.41; low-certainty evidence; Analysis 2.1). Six studies of 639 participants reported pain intensity at follow-up (12 months) (Dworkin 1994; Dworkin 2002a; Dworkin 2002b; Gatchel 2006; Litt 2010; Mishra 2000). The SMD suggested a small effect in favour of CBT (SMD -0.30, CI -0.51 to -0.09; P = 0.004; low-certainty evidence; Analysis 2.2). At follow-up, at least 30% pain intensity was reported for CBT in all included studies. Findings were inconsistent within the control groups (Table 1).

Disability caused by pain

Pain disability at treatment completion was reported by three studies of 315 participants. No evidence was found for a difference between CBT and control (SMD 0.02, CI -0.21 to 0.24; P = 0.88, I^2 = 0%; low-certainty evidence; Analysis 2.3). At follow-up, two studies of 240 participants reported disability and I^2 was 83%. No evidence was found for a difference between CBT and control (SMD 0.01, CI -0.61 to 0.64; P = 0.97; low-certainty evidence; Analysis 2.4).

Adverse events

Adverse events were reported only by Litt 2010, who reported worsening symptoms in 13 people treated with an oral splint and four treated with CBT.

Secondary outcomes

Psychological distress

Psychological distress was only reported by Litt 2010. No evidence of a difference was found between CBT and standard treatment at completion (MD 2.36, 95% CI -1.17 to 5.89; P = 0.19; low-certainty evidence; Analysis 2.5), or at follow-up (MD -1.02, 95% CI -4.02 to 1.98; P = 0.51; low-certainty evidence; Analysis 2.6).

Additional physical symptoms

This outcome was not measured.

Quality of life

This outcome was not measured.

GRADE assessment

We downgraded the certainty of the evidence by two levels for all outcomes other than adverse events, based on imprecision and risk of bias. Therefore our confidence that the results represent a true effect is low. We downgraded reported results on adverse events by three levels, resulting in a judgement of very low confidence in the results due to inconsistency, imprecision and limitations in study quality (high risk of bias across many of the domains assessed).

Subgroup analyses

Time since TMD onset (> 3 months and ≤ 12 months versus > 12 months) and extent of TMD disability

We found insufficient data to conduct our planned subgroup analyses based on TMD of less than 12 months versus TMD of more than 12 months, or of low versus high disability.

Gatchel 2006 reported promising results from a study of people reporting painful TMD for 12 months or less and who were classed as having a 'high risk' of disabiliity using a predictive algorithm developed by the study authors. These participants were randomised into an early intervention group, receiving six sessions of CBT and biofeedback, or a non-intervention group. They reported that, after a year, participants of the early intervention group reported significantly less pain and emotional distress than the non-intervention group. Moreover, while the early intervention group had improved on these measures, the non-intervention group had become worse.

For those with a longer history of painful TMD, some studies reported differential outcomes depending on various psychological factors measured at baseline. Dworkin 2002a reported significant

improvements in pain intensity, activity interference and somatisation from a three session 'self-care' intervention delivered by trained dental hygienists for people graded as having low disability on the Graded Chronic Pain Scale. For those graded as having high disability, a more intensive psychological intervention led by a psychologist and dentist resulted in immediate improvements in pain intensity and activity interference that were not maintained at 1-year follow-up.

Participant age (12 to 17 years versus 18 years and above)

Of the studies included in the review, 20 referred to an adult population (age 18 years or older). Two studies reported outcomes with adolescents. The first, Wahlund 2003, reported that adolescents who received brief information plus an occlusal appliance reported significantly lower pain intensity at treatment completion than those who received brief information and relaxation training. Of those adolescents in the occlusal appliance group, 60% reported at least a 50% reduction in pain by the end of treatment compared to 32% of those in the brief information and relaxation group. The trial authors thought the relatively weak results from relaxation training may be related to the low number of sessions offered (4 individual sessions). A further study by Wahlund 2015 compared an occlusal appliance to eight individual relaxation sessions of 45 minutes each plus instructions for 15 minutes daily home practice. At treatment completion, 62.1% of adolescents in the occlusal appliance group reported that they were completely well or very much improved compared to 17.9% in the relaxation group. At six months, 79.2% of those in the occlusal appliance group and 60% in the relaxation group reported being completely well or very much improved. We did not find any studies reporting on other psychological therapies for people in the adolescent age group.

Other psychological therapies versus control (no treatment, waiting list or usual care)

The clinical heterogeneity of other psychological therapies and comparisons meant that it was impractical to combine them in meta-analysis as planned. This was due not only to the variety of interventions described, but due to some elements such as relaxation or education being included in some studies as part of the intervention and in others as comparisons. We looked only at what the studies found for pain intensity and adverse events.

Pain intensity

We calculated a clinically significant improvement in pain for each study. We based our calculations on a reduction of at least 30% from baseline of reported pain, in line with published recommendations for estimating clinically-important pain reduction (Al-Baghdadi 2014; Dworkin 2005; Farrar 2001; Smith 2020). Data regarding which studies reported at least a 30% pain reduction from baseline are presented in Table 1. Based on this metric, there is limited evidence that psychological treatments, other than CBT, are consistently beneficial in terms of percentage pain reduction measured at treatment completion or follow-up. It should be noted that these are within-group comparisons and not a comparison between the intervention and control, therefore breaking the purpose of the randomisation.

Table 2 presents percentage reduction data alongside the mean difference (MD) in pain intensity scores between groups at end of treatment/follow-up. There remains limited evidence to demonstrate that psychological treatments other than CBT are beneficial in terms of pain intensity reduction. Any evidence of an effect comes from individual trials at high risk of bias.

Adverse events

Two studies of psychological therapies other than CBT reported data on adverse events. Wahlund 2015 reported no adverse treatment effects from treatment with an occlusal appliance or with relaxation therapy. Abrahamsen 2011 reported that one participant who received hypnosis was admitted to a psychiatric hospital during the intervention. According to the study authors, the admission was for reasons unrelated to the study treatment. The other studies did not report whether or not there were adverse events.

DISCUSSION

Summary of main results

We included 22 studies in this review: 13 evaluated CBT; two evaluated relaxation as the experimental condition, and one study evaluated each of mindfulness, hypnosis, mixed CBT and hypnosis, a habit reversal treatment, education and counselling, and a hope-based intervention. Just over half of the studies used an active comparison, which included oral splints, medications, education and relaxation. The other studies used a usual care or no-treatment (waiting list) control.

The studies were conducted over a period of more than 40 years. Twelve studies presented data on at least one outcome suitable for meta-analysis and ten studies reported in a format that could not be included in meta-analyses. There were high levels of heterogeneity, both in terms of reported results and also study design, comparators, nature and intensity of the psychological treatment and length and severity of symptoms. Using the GRADE approach, we judged our confidence in most effect sizes as low, meaning that reported effect sizes may not represent the true effect size in the wider population.

We carried out an analysis of CBT against alternative treatment and against control. For studies that reported data that could not be included in the meta-analyses, we reported on whether treatment and alternative or control conditions achieved a minimum reduction in pain intensity of 30%. CBT interventions did not differ from alternative or control conditions for pain intensity at treatment completion, but showed a small advantage over other conditions at follow-up. There were no differences evident in terms of pain disability between CBT and other alternative or control conditions. Treatment with CBT showed a small advantage in reducing psychological distress at treatment completion and follow-up compared to alternative treatment. Only one study comparing CBT against control reported psychological distress as an outcome.

Summary of outcomes across comparisons

Pain intensity

There was no evidence of a benefit of CBT against alternative treatment or control at treatment completion for pain intensity. At follow-up, CBT showed a small advantage compared to alternative treatment and control. There was insufficient evidence to judge whether other psychological therapies had an effect on pain intensity.

Pain disability

There was no evidence of a difference in disability outcomes between CBT and alternative treatments or control at treatment completion or follow-up. There was insufficient evidence for other forms of psychological treatment.

Psychological distress

CBT showed a small advantage over alternative treatments in terms of distress at treatment completion and follow-up. There was only one study evaluating CBT against control (usual care), which did not find evidence of a difference between them for psychological distress. There was insufficient evidence to judge the impact of psychological therapies other than CBT on psychological distress in TMD.

Adverse events

Only six studies presented information on adverse events. From the data available, adverse effects associated with psychological treatment tended to be minor and to occur less often than in alternative treatment groups. There was, however, insufficient evidence presented in order to come to a firm conclusion.

Other outcomes

There were insufficient data present on our other outcomes (quality of life and additional physical symptoms) to come to any conclusions. Only one study reported data for each of these outcomes.

Overall completeness and applicability of evidence

Of the studies reported, a relatively high proportion (10 out of 22) included data in a form that could not be combined in meta-analysis. This was because of the difficulty of grouping heterogenous clinical interventions, or because standard deviations (SDs) or numbers of participants in each group were not reported and we were not able to gain access to this information by writing to the study authors. Studies that did include data that we combined did not tend to report duration or complexity of symptoms prior to treatment. The majority of the studies were carried out in specialist treatment centres and in countries with high levels of health literacy and access to psychological services. Only 11 studies in total reported on pain intensity at follow-up (5 against alternative treatment, 6 against control). There is, therefore, little evidence available about the long-term impact of psychological therapy on ongoing symptoms.

It is also of note that three studies (Dworkin 2002a; Dworkin 2002b; Gatchel 2006), selected specific subgroups of people with TMD for inclusion based on clear rationale of who would be more likely to benefit from psychological treatment. Gatchel 2006 included people early in the experience of TMD who were judged to be at 'high risk' of complexity. Dworkin 2002a and Dworkin 2002b separated participants into two groups based on their Graded Chronic Pain Scale classification and provided tailored treatment, which involved a lower intensity treatment for those with low levels of disability and a more intensive treatment for those with higher levels of disability. The outcomes reported in these papers, particularly for people with recent onset pain and lower disability, are positive. Reports from these studies provide preliminary evidence that it may be beneficial to 'match' people to psychological treatments depending on how long they have had pain and on measures of disability. Unfortunately, there is currently not enough evidence available to judge whether such an approach would be effective on a larger scale.

We did not carry out separate analyses as planned of BT and other forms of psychological therapy due to the small numbers (2 studies on hypnosis, 2 on relaxation, 1 on BT, 1 on mindfulness, 1 on education and 1 hope-based intervention). None of the studies evaluated ACT, compassion-focused or cognitive functional therapy, even though these are commonly used interventions for persistent pain elsewhere in the body (Penlington 2019b).

Certainty of the evidence

Our certainty in the evidence as a whole was low. We downgraded our confidence in the effects of treatment across most outcomes due to significant imprecision and risk of bias. Adverse events were infrequently reported and our confidence that these were representative was therefore very low. There is, therefore, a high likelihood that further research could change the estimates of effect size reported in this review.

Potential biases in the review process

We aimed to reduce bias by publishing the protocol for this review in advance and by at least two members of the team independently screening the studies, extracting data and assessing risk of bias and evidence certainty. As planned in our study protocol, we only included RCTs where one of the treatment arms involved psychological treatment delivered by qualified psychologists or therapists trained and supervised in the treatment approach specified. We also aimed to reduce bias by selecting outcome measures in advance of finding studies and extracting data. The three main outcomes of pain intensity, pain disability and distress are plausible, meaningful outcomes that are highly likely to be of relevance to this population.

Our database searches (see Appendices) were thorough and inclusive, and included a search of the grey literature; we therefore believe it likely that we have included all relevant studies.

Agreements and disagreements with other studies or reviews

This is the first Cochrane Review of psychological therapies specifically for painful TMD. The findings are broadly consistent with the recent Cochrane Review of 'Psychological therapies for the management of chronic pain (excluding headache) in adults' (Williams 2020). Our findings that CBT was associated with small or very small benefits at treatment completion and follow-up compared to alternative treatments or usual care are similar to those of Williams 2020. However, we did not find any benefit of psychological treatments on disability outcomes, whereas Williams 2020 did report a small benefit of psychological therapy on this dimension. This could be because Williams 2020 includes more recent trials; the specific targeting of pain disability has been a feature of more recent psychological approaches to managing pain. It could also reflect inherent differences between specific TMD pain and more general chronic pain, or simply a measurement effect. The number and assessed quality of included studies was somewhat lower in our review compared to Williams 2020. We had far less data about approaches other than CBT, but findings of both reviews were still broadly in line for psychological therapies, indicating small benefits of CBT and little to no evidence

for psychological therapies other than CBT in this population. Certainly, for this review, this reflects a lack of studies of alternative psychological treatment approaches and this is also broadly in line with Williams 2020.

The findings are also in keeping with a number of reviews of psychological therapies for TMD carried out within the past decade. Aggarwal 2010 reviewed studies of CBT for chronic orofacial pain and reported weak evidence to favour the use of CBT in secondary care, but commented that there was little research into the optimal duration or content of sessions, or to suggest that it could be implemented in primary care settings. Liu 2012 reviewed a selection of studies reporting on the effectiveness of CBT for painful TMD and concluded that the effect of CBT was inconsistent between studies, so no firm conclusions could be drawn. Randhawa 2016 also reviewed a selection of the published studies (those that they considered to be at low risk of bias) and suggested that CBT has similar effects to self-management for the outcome of pain, but that CBT was superior for pain disability and distress. Although our findings are broadly consistent with all of these reviews, there are some small differences, which can be accounted for by slightly different inclusion criteria. The ability of such slight differences in study selection to influence the findings in this way is an indication of the need for caution in interpreting the results.

Our findings are also consistent with a review by Kotiranta 2014 into tailored treatments for TMD. This review concluded that, where treatments were hypothesised to be suitable for a particular group based on psychosocial or related characteristics of the group, the outcomes of CBT in people with TMD offered this intervention tended to be favourable. While very few trials have taken this approach (and no additional trials since the publication of the review by Kotiranta 2014), we tentatively came to the same conclusion.

AUTHORS' CONCLUSIONS

Implications for practice

Consistent with previous reviews, the results of this review show that people who receive psychological treatments (specifically, CBT) for painful TMDs may have slightly less pain and be less distressed at long-term follow-up than people who received an alternative treatment or no treatment. However, this difference is small, may not be clinically significant, and for pain intensity is not evident at the point of treatment completion. Our confidence that these results represent a true finding is low, based on characteristics of the evidence that have been reported to date.

The evidence to date is mainly for CBT, and there is very little evidence available about alternative psychological treatment approaches; however, this may not represent a lack of efficacy; there is simply insufficient evidence to make a judgement. The evidence available at the present time does not suggest that CBT or other psychological interventions are, on average, superior to other available interventions.

Little is known about adverse effects that might be associated with psychological treatment. From information that has been reported, psychological treatments may be associated less frequently with adverse effects compared to other available treatments such as medications or oral appliances.

Healthcare professionals who are not psychologists can consider referring people for psychological therapies as a primary management strategy if this is the patient's preference, and they are able to access psychological therapy locally without a long wait.

For psychology professionals, in the absence of evidence about the superiority of one psychological therapy over another, treatment decisions should continue to be based on a careful assessment of each patient, including a formulation of individual factors that may contribute to their ability to engage effectively in self-management, and regular review of the impact of treatment.

In the absence of further clarity about these findings, none of which are robust, clinicians in practice may consider psychological treatment as a potential intervention for painful TMD. In order to assess the efficacy of psychological therapies for key outcomes, people should be followed up for as long as possible after treatment completion.

Implications for research

There is a need for further, good-quality research trials of psychological therapies for painful TMDs. These should cover a range of psychological approaches, including CBT and also other treatment approaches such as BT, ACT and CFT, which are currently under-researched for TMD. Specific intensities of treatments should be targeted to individual characteristics, with a clear hypothesis of why a certain intervention is thought to be suitable for a certain subset of people. When planning the intervention, researchers should be guided by research into psychological treatments for chronic pain in general, and should not restrict their consideration to research specifically into TMD, which may be limited. Since average effects are small, researchers should consider aiming to identify specific individual characteristics or potential change processes that might address the question of which treatment is most suitable in which situation, rather than aiming to answer a blanket question of which is the best treatment approach.

Data collection should include measures of pain intensity, pain disability and psychological distress, and should continue ideally until at least 12 months post-treatment. Researchers should be explicit about whether studies are targeting people with TMD in a community, primary care or secondary/tertiary care setting. Since very few studies have been carried out to date in the community or primary care, there is a particular need for high-quality, pragmatic RCTs in primary care and the community settings that mimic the real-world conditions in which these treatments might be applied.

There is also a particular need for good-quality RCTs of psychological therapies for TMD in adolescents, as it is common for symptoms to start at this age. We found only two relevant studies from one group that focused on adolescents, and these used relaxation as an intervention. Researchers should consider planning good-quality trials of psychological therapies against alternative treatments (such as oral splints) or usual care, and include longer-term follow-up data.

ACKNOWLEDGEMENTS

We acknowledge the contribution of Cochrane Oral Health to the production of the protocol and the review, specifically Laura MacDonald, Managing Editor; Anne Littlewood, Information Specialist; Professor Anne-Marie Glenny, Co-ordinating Editor;

Editors Zipporah Iheozor-Ejiofor, Dr Jennifer Taylor, and Dr Philip Riley; Claudia Bollig and Annette Bluemle for translations; and copy-editors Deirdre Walsh, Andrea Takeda and Claire Dooley. We also thank peer reviewers Pauline Adair, Iris Gordon and Ranjana Garg. Thank you to Niki Jones for contributing to the plain language summary.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Abrahamsen 2011

Study characteristics

Abrahamsen 2011 *(Continued)*

Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 1
Participants	**Inclusion criteria:** RDC/TMD diagnosis of persistent myofascial pain disorder of over 6 months. Comorbidities and stable doses of pain medication did not preclude inclusion. **Exclusion criteria:** pacemaker, severe psychiatric illness **Pretreatment:** largely similar at baseline **Number eligible for study:** not stated **Number of participants:** 43 **Number randomly assigned to intervention (control):** 21 in hypnosis group, 22 in relaxation (control) group **Number started treatment in intervention (control):** 20 (20) **Number completed treatment in intervention (control):** 19 (15) **Number included in analysis from intervention (control):** 20 **Comorbidity:** not stated **Sex:** 100% female **Ethnicity:** not specified **Other sample characteristics:** n/a
Interventions	• Hypnosis • Relaxation (control)
Outcomes	• Characteristic Pain Intensity • Average daily pain intensity (NRS) • Psychological distress (SCL-60) Used in study but not in review: • Hypnotic suggestibility • Blink reflex • Coping strategies questionnaire • RDC examination and questionnaires • McGill Pain questionnaire • Pittsburgh sleep quality index • Medication intake
Identification	**Date of study:** 2007 to 2008; specific date not mentioned. Paper published 2011 **Sponsorship source:** not stated

Abrahamsen 2011 *(Continued)*

	Setting: dental hospital **Author name:** Randi Abrahamsen **Institution:** Aarhus University Hospital **Email:** lbhansen@odont.au.dk (second author Lene Baad Hansen) **Address:** Department of Clinical Oral Physiology, School of Dentistry, Aarhus University, Vennelyst Boulevard 9, DK-8000 Aarhus C, Denmark
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer randomisation. Quote: "Patients were randomly assigned (randomisation computer program) to a hypnosis group (n = 21) or a control group with nonhypnotic relaxation as the intervention (n = 22)."
Allocation concealment (selection bias)	Unclear risk	Detail not provided about steps taken to ensure group allocation could not be predicted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were told they were in an active treatment group and that two treatment groups were being compared against each other. Blinding of clinician is not possible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes - participants completed their own assessments and were not blind to treatment received
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	States intention-to-treat but did not account for 1 participant (of 20) with missing data
Selective reporting (reporting bias)	Low risk	Outcomes are reported as planned in the methods section.
Other bias	Low risk	None noted

Bartley 2019

Study characteristics

Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 1
Participants	**Inclusion criteria:** adults recruited from the local community reporting moderate facial pain (3 ± 10) on at least 15 days for the past 3 months. Evaluated in clinic by RDC/TMD examination **Exclusion criteria:** < 18 or > 65 years of age, use of narcotic analgesics, use of nonsteroidal anti-inflammatory medications 24 hours before pain testing sessions, cardiovascular, neuroendocrine or neurological disorders, cognitive impairment

Bartley 2019 *(Continued)*

Pretreatment: no significant differences between groups at baseline

Number eligible for study: 35

Number of participants: 33

Number randomly assigned to intervention (control): 16 (17)

Number started treatment in intervention (control): 16 (17)

Number completed treatment in intervention (control): 15 (14)

Number included in analysis from intervention (control): 15 (14)

Comorbidity: not discussed

Sex: not reported

Ethnicity: white 21, black 6, other 2

Other sample characteristics: n/a

Interventions	• Hope-based intervention - 3 sessions informed by Snyder's cognitive theory of hope, covering goal pursuit, pathways thinking and agency • Education about pain and stress (control)
Outcomes	• CES-D Depression scale Used in study but not in review: • Adult State Hope Scale (measures related to sensory testing including numerical pain rating scale (0 to 100) in relation to various sensory tests) • Positive and Negative Affect Scale • Chronic Pain Acceptance Questionnaire • Pain Self-Efficacy Questionnaire • Pain Catastrophizing Scale • Various other measures
Identification	**Date of study:** article published 2019. Unclear when study took place **Sponsorship source:** American Pain Society Sharon S Keller Grant **Country:** USA **Setting:** University of Florida Clinical Research Center **Author:** Emily J Bartley **Institution:** University of Florida **Email:** ebartley@dental.ufl.edu **Address:** Pain Research and Intervention Center of Excellence, College of Dentistry, University of Florida, 1329 SW 16th St, Suite 5192, Gainesville, FL 32610
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Method not described

Bartley 2019 *(Continued)*

		"Participants...were randomly assigned by the PI following simple randomisation procedures (accounting for equal distribution of men and women across groups)"
Allocation concealment (selection bias)	Unclear risk	Does not say whether principal investigator who performed random allocation was blinded
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not discussed. Not possible for this kind of study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research assistants were blind to group allocation. Participants were told they were randomised to one of two active interventions.
Incomplete outcome data (attrition bias) All outcomes	Low risk	29 out of 33 participants completed study
Selective reporting (reporting bias)	Low risk	Comprehensive data are presented as described in the methods.
Other bias	Low risk	None noted

Calderon 2011

Study characteristics	
Methods	**Study design:** parallel-group RCT **Number of control groups:** 2 **Number of intervention groups:** 2
Participants	**Inclusion criteria:** history of orofacial pain for more than 6 months, pain occurring daily or almost daily for at least the month preceding enrolment, pain of at least moderate severity (i.e. at least 40 mm on a visual scale of 0 to 100 mm), age ranging from 17 to 55 years **Exclusion criteria:** major neurological or psychiatric disorders, glaucoma, history of intolerance to amitriptyline, pain secondary to trigeminal neuralgia, or pain attributable to other local, well defined condition **Pretreatment:** no statistically significant differences at baseline between groups **Number eligible for study:** 60 **Number of participants:** 47 **Number randomly assigned to intervention (control):** 23 (24) **Number started treatment in intervention (control):** 23 (24) **Number completed treatment in intervention (control):** 17 (20) **Number included in analysis from intervention (control):** 17 (20) **Comorbidity:** not specified **Sex:** all female

Calderon 2011 *(Continued)*

	Ethnicity: not reported **Age:** 35.4 or 35.6 years (reported differently in abstract and main text) (range 17-52 years) **Other sample characteristics:** n/a
Interventions	• CBT plus amitriptyline 25 mg • CBT plus placebo • Amitriptyline 25 mg • Placebo
Outcomes	• VAS for pain • BDI • Oral Health Impact Profile (modified) Used in study but not review: • Pittsburg Sleep Quality Index
Identification	**Date of study:** paper published in 2011. Study dates not specified **Sponsorship source:** CAPES - Brazil **Setting:** outpatient university based orofacial pain clinic **Author:** Patricia S Calderon **Institution:** Universidade Federal do Rio Grande do Norte **Country:** Brazil **Email:** patriciascalderon@yahoo.com.br **Address:** Departamento de Odontologia, Universidade Federal do Rio Grande do Norte, Avenida Salgado Filho, 1787, Lagoa Nova, 59056-000 Natal, RN, Brasil
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was stratified by pain level and generated using the web site 'www.randomization.com' by a researcher unrelated to the rest of the study.
Allocation concealment (selection bias)	Low risk	"The randomisation scheme was generated using the web site 'www.randomization.com' and the researcher was blind to group distribution. Then, a different person was designated to allocate the patients in their groups, for the medicine distribution and to lead the patients to the CBT."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of participants and personnel not possible for the psychological element of the study. Placebo used to blind to medication and administered by an independent person
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not stated
Incomplete outcome data (attrition bias)	High risk	Data from participants who dropped out were not included in the analysis.

Calderon 2011 *(Continued)*

All outcomes		"9 patients dropped out from the study and 1 was excluded from the study due to adverse events (self-report visual symptoms after taking the medicine)"
Selective reporting (reporting bias)	Low risk	Outcomes reported for all measures described in methods
Other bias	Low risk	None noted

Dworkin 1994

Study characteristics	
Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 1
Participants	**Inclusion criteria:** referral for treatment of TMD with a self-report of facial ache/pain in muscles of mastication; TMJ; pre- and intra-auricular **Exclusion criteria:** pain attributable to: confirmed migraine or head pain condition (other than tension headache), acute infection, significant disease of teeth, ears, eyes, nose or throat, history of significant or debilitating chronic physical or mental illness, requiring emergency TMD treatment **Pretreatment:** none **Number eligible for study:** 395 **Number of participants:** 185 **Number randomly assigned to intervention (control):** 95 (90) **Number started treatment in intervention (control):** 95 (90) **Number completed treatment in intervention (control):** 66 (73) **Number included in analysis from intervention (control):** 66 (73) **Comorbidity:** major conditions excluded, otherwise not stated **Sex:** 85% female, 15% male **Ethnicity:** 96% white **Other sample characteristics:** 81% completed more than high school education
Interventions	• Brief CBT • Usual care
Outcomes	• Characteristic Pain Intensity Used in study but not review: • SCL-90 depression and somatisation scales

Dworkin 1994 *(Continued)*

- Pain interference dichotomised on GCPS
- Participant rating of change

Identification	**Date of study:** not reported - paper published 1994 **Sponsorship source:** NIDR Program Project Grant **Country:** USA **Setting:** School of Medicine - TMJ Clinic of Group Health Cooperative of Puget Sound (GHC) or Orofacial Pain and Dysfunction Clinic at the University of Washington School of Dentistry (VW) **Author name:** Samuel F Dworkin **Institution:** University of Washington **Email:** none provided **Address:** Department of Oral Medicine, School of Medicine, University of Washington, Seattle, WA 98195, USA
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation schedule
Allocation concealment (selection bias)	High risk	Allocation concealment not discussed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants to this kind of study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome data collected by dental hygienists who were unaware of group allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participants who dropped out were asked to complete measures in order to allow for an intention-to-treat analysis.
Selective reporting (reporting bias)	Low risk	A comprehensive list of outcomes is reported.
Other bias	Low risk	None observed

Dworkin 2002a

Study characteristics

Methods	**Study design:** parallel-group RCT

Dworkin 2002a *(Continued)*

Number of control groups: 1

Number of intervention groups: 1

Participants	**Inclusion criteria:** self-reported facial pain or ache in region of TMD muscles, diagnosed TMD according to RDC/TMD criteria GCPS group of 0, 1 or 2a, aged 18 to 70 **Exclusion criteria:** pain according to confirmed migraine or head pain other than tension headache acute infection of teeth or facial area presence of significant or debilitating physical or mental health condition necessity for urgent TMD treatment **Pretreatment:** no significant difference between groups at baseline other than higher level of education attained with 91.8% of self-care compared to 57.7% of usual treatment reporting post-high school education. Baseline measures adjusted for level of education. **Number eligible for study:** 196 **Number of participants:** 124 **Number randomly assigned to intervention (control):** 61 (63) **Number started treatment in intervention (control):** 48 (55) **Number completed treatment in intervention (control):** 43 - 61 randomised, 13 dropped out before any sessions, 5 dropped out after up to 2 sessions (51 - 63 randomised, 8 dropped out before any treatment, 4 dropped out from treatment) **Number included in analysis from intervention (control):** analyses are on intention-to-treat basis where data allows. 90% data from those who started treatment available at follow-up: of 48 patients who began the self-care intervention, 5 dropped out, and of the 55 patients who began the usual treatment arm, 4 dropped out. **Comorbidity:** not stated except for exclusion of significantly debilitating comorbidities **Sex:** 85 female, 15 male **Ethnicity:** not stated **Other sample characteristics:** more of the self care group had education beyond high school level. This was therefore adjusted for in the analyses.
Interventions	• CBT-based self-care intervention: a 3-session intervention led by dental hygienists trained and supervised by a clinical psychologist. Treatment followed cognitive-behavioural principles and consisted of education, guided reading with structured feedback, relaxation and stress management training, self-monitoring of signs and symptoms, development of a personal TMD self-care plan, supervised practice and reinforcement of dentist prescribed self-care treatments and maintenance and relapse prevention. • Usual treatment
Outcomes	• Pain intensity - CPI scale of GCPS • Pain-related interference in activities - average of 0 to 10 ratings of pain-related interference with work, social and overall activities Used in study but not in review: • RDC/TMD axis 1 physical examination measures including range of vertical mandibular motion, number of extra- and intraoral masticatory muscles painful to palpation • Pain-related disability days: number in the past 6 months

Dworkin 2002a *(Continued)*

- SCL-90-R scales: scale scores for depression and number of non-specific physical symptoms
- Days in pain in prior 6 months
- Number of co-occurring pain problems
- Number of pain-related visits in last 12 months
- Global satisfaction, compliance, participation and visits related to health in last 12 months
- Coping and perceived control measured by pain beliefs, coping and behaviour numerical scales on 0 to 5 rating scale

Identification	**Date of study:** published 2002 **Sponsorship source:** National Institute of Dental and Craniofacial Research **Country:** USA **Setting:** specialist orofacial pain clinic connected to a university **Comments:** comprehensive care **Author name:** Samuel Dworkin **Institution:** University of Washington **Email:** dworkin@u.washington.edu **Address:** Department of Oral Medicine and Psychiatry and Behavioural Sciences
Notes	Raw data not available in article

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Method of sequence generation not discussed
Allocation concealment (selection bias)	High risk	Allocation concealment not specified
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of participants not possible in this type of intervention. Blinding of study personnel not discussed
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of outcome assessors not discussed
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data are reported where possible on an intention-to-treat basis.
Selective reporting (reporting bias)	Low risk	Results are presented from the broad range of outcome measures.
Other bias	Low risk	None noted

Dworkin 2002b

Study characteristics	
Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 1
Participants	**Inclusion criteria:** self-report of facial ache or pain in TMD relevant areas, RDC/TMD based diagnosis, Grade 2b, 3 or 4 on GCPS, attending dentist judges treatment needed **Exclusion criteria:** pain attributable to confirmed migraine or facial condition other than tension headache, acute infection or other significant disease relevant to the face, debilitating physical or mental health condition, requires urgent treatment for TMD, unable to communicate in English **Pretreatment:** groups largely similar at baseline **Number eligible for study:** 186 **Number of participants:** 117 **Number randomly assigned to intervention (control):** 59 (58) **Number started treatment in intervention (control):** not stated **Number completed treatment in intervention (control):** not stated **Number included in analysis from intervention (control):** 52 post-treatment and 56 at 12 months in intervention group. 49 post-treatment and 51 at 12 months in control. **Comorbidity:** not mentioned. Major comorbidities excluded **Sex:** 100 female, 17 male **Ethnicity:** not stated **Other sample characteristics:** defined as complex on basis of 2b or higher rank on GCPS
Interventions	• Comprehensive care (6 session high intensity CBT-based treatment) • Usual care
Outcomes	• Pain intensity - CPI scale of GCPS • Pain-related interference in activities - average of 0 to 10 ratings of pain-related interference with work, social and overall activities Used in study but not in review: • RDC/TMD axis 1 physical examination measures including range of vertical mandibular motion, number of extra- and intraoral masticatory muscles painful to palpation • Pain-related disability days: number in the past 6 months • SCL-90-R scales: scale scores for depression and number of non-specific physical symptoms • Days in pain in prior 6 months • Number of co-occurring pain problems • Number of pain-related visits in last 12 months • Global satisfaction, compliance, participation and visits related to health in last 12 months • Coping and perceived control measured by pain beliefs, coping and behaviour numerical scales on 0 to 5 rating scale

Dworkin 2002b *(Continued)*

Identification	**Date of study:** published 2002 **Sponsorship source:** National Institute of Dental and Craniofacial Research **Country:** USA **Setting:** specialist orofacial pain clinic connected to a university **Author name:** Samuel Dworkin **Institution:** University of Washington **Email:** dworkin@u.washington.edu **Address:** Department of Oral Medicine and Psychiatry and Behavioural Sciences
Notes	Raw data not available in article

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Method of sequence generation not discussed
Allocation concealment (selection bias)	High risk	Not discussed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of participants not possible in this type of intervention Blinding of study personnel not discussed
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not discussed
Incomplete outcome data (attrition bias) All outcomes	High risk	Although efforts were made for an intention-to treat analysis, data were missing from 16 participants at treatment follow-up and 10 at 1 year follow-up
Selective reporting (reporting bias)	Unclear risk	All measures collected are reported in the text. Most, however, do not include raw data that can be included in meta-analysis.
Other bias	Low risk	None noted

Ferrando 2012

Study characteristics

Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 1
Participants	**Inclusion criteria:** TMD muscular subgroup diagnosis (group 1 axis I diagnosis) following RDC/TMD2, intellectual ability to follow the evaluation process and psychologic intervention

Ferrando 2012 *(Continued)*

	Excluded criteria: abnormalities, such as facial deformity, tumoral pathology, or lesions of the oral mucosa (e.g. erosive lichen planus, pemphigus, pemphigoids, or large aphthae), evidence in medical records of psychotic disorders according to the DSM **Pretreatment:** no significant differences in group allocation **Number eligible for study:** 85 **Number of participants:** 72 **Number randomly assigned to intervention (control):** 41 (31) **Number started treatment in intervention (control):** 41 (31) **Number completed treatment in intervention (control):** 30 (29) **Number included in analysis from intervention (control):** 30 (29) **Comorbidity:** not specified **Sex:** 52 female, 7 male **Ethnicity:** not specified **Other sample characteristics:** n/a
Interventions	• CBT/hypnosis - 6 sessions • Usual care
Outcomes	• GCPS • Pain intensity (Von Korff 1992) Used in study but not review: • MPI interference scale • Brief Symptom Inventory • Pain Catastrophizing Scale • Coping Pain Questionnaire • Pain frequency • Self-medication • Subjective Pain Index of the WHYMPI (Kerns 1985, Spanish version, Andreu 2006) • Number of localised sites according to RDC/TMD criteria • Number of painful points on pressure • Emotional Distress Symptom Inventory (including subdimensions anxiety, somatisation and depression)
Identification	**Date of study:** original paper published 2012 **Sponsorship source:** research was funded by the Spanish Ministry of Science and Technology (SEJ2009-02440) and the Valencian Regional Government of Industry, University and Science (GV06/373) **Setting:** stomatology clinic at Stomatology Department Valencia University General Hospital **Country:** Spain **Author name:** Maite Ferrando **Institution:** University of Valencia and Valencia University General Hospital, Valencia, Spain **Email:** teresa.ferrando@uv.es

Ferrando 2012 *(Continued)*

	Address: Department of Personality, Assessment, and Psychologic Treatments, University of Valencia
Notes	This study is also reported in Dura-Ferrendis 2017, which adds interesting insights but no additional data.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer programme for random number generation
Allocation concealment (selection bias)	Low risk	Allocation according to previously defined criteria and random number allocation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants in this kind of trial. Study personnel blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	No intention-to-treat analysis. Data from 11 people who dropped out of the intervention group not included
Selective reporting (reporting bias)	Low risk	Table of results presents all outcomes
Other bias	Low risk	None noted

Gatchel 2006

Study characteristics

Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 1
Participants	**Inclusion criteria:** adults age 18 to 70 years, jaw or facial pain present for less than 6 months **Exclusion criteria:** comorbid pain-exacerbating physical condition (such as cancer or fibromyalgia), history of jaw pain before the most recent episode **Pretreatment:** no significant demographic differences at baseline. **Number eligible for study:** 101 **Number of participants:** 101 **Number randomly assigned to intervention (control):** 56 (45) **Number started treatment in intervention (control):** 56 (45) **Number completed treatment in intervention (control):** 54 (45)

Gatchel 2006 *(Continued)*

	Number included in analysis from intervention (control): 54 (45) **Comorbidity:** major comorbidities excluded **Sex:** female 80.5%, male 19.5% **Ethnicity:** white 78.5%, Hispanic 12%, African American 8%, Asian 4.5%, other 3% **Other sample characteristics:** marital status, employment status, health/dental insurance, education, income, referrer
Interventions	• CBT/biofeedback • Usual care
Outcomes	• CPI • BDI Used in study but not review: • Ways of Coping Questionnaire • West Haven-Yale MPI • Schedule for Nonadaptive and Adaptive Personality • Structured Clinical Interview based on DSM • Physical examination based on RDC • Chewing performance evaluation
Identification	**Date of study:** paper published 2006 **Sponsorship source:** supported in part by National Institutes of Health grants 2R01 DE10713, 2R01 MH46452 and 1K05 MH071892 **Setting:** specialist TMD clinic, TMD clinical research programme **Country:** USA **Author name:** Robert J Gatchel **Institution:** University of Texas at Arlington **Email:** gatchel@uta.edu **Address:** Department of Psychology, College of Science, University of Texas at Arlington, 313 Life ScienceBuilding, 501 S. Nedderman Drive, Arlington, Texas 76019-0528
Notes	Early intervention group participants were more likely to also seek additional treatment from a range of other practitioners during the study period, which could account for some differences in outcome.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Details of randomisation method not given
Allocation concealment (selection bias)	High risk	Details not given
Blinding of participants and personnel (performance bias)	High risk	Not possible to blind participants to this kind of treatment. Blinding of study personnel not mentioned

Gatchel 2006 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of outcome assessors not discussed
Incomplete outcome data (attrition bias) All outcomes	Low risk	98 of 101 participants completed 1-year follow-up
Selective reporting (reporting bias)	Low risk	Clearly defined outcome measures with good rationale described and thoroughly reported
Other bias	Unclear risk	Note although mean duration of TMD is 97 days, it was not possible to separate participants who had experienced symptoms for less than 3 months. Participants in the treatment group were more likely to also seek other forms of treatment, which could influence outcome

Litt 2010

Study characteristics	
Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 1
Participants	**Inclusion criteria:** positive Axis I diagnosis on the RDC/TMD bilateral or unilateral pain in the area of the TMJ that had persisted and was noticeable on a daily basis for a period of at least 3 months **Exclusion criteria:** contraindication to TMD treatment, lack of fluency in English (as determined by inability to read and understand a statement of informed consent), previous surgery for treatment of TMD pain, history of rheumatoid disease, extensive anatomical destruction or deterioration of the TMJ, diagnosed as having pain of neuropathic or odontogenic origin, diagnosis of psychosis, current use of antidepressants or anxiolytics, taking opioid pain medication, pregnancy (due to possible adverse effects in pregnancy with the prescription of non-steroidal anti-inflammatory drugs) **Pretreatment:** not explicitly addressed **Number eligible for study:** 121 **Number of participants:** 101 **Number randomly assigned to intervention (control):** 52 (49) **Number started treatment in intervention (control):** 52 (49) **Number completed treatment in intervention (control):** 52 (49) **Number included in analysis from intervention (control):** 52 (49) **Comorbidity:** not discussed other than exclusions **Sex:** 85 female, 16 male **Ethnicity:** white (79%), black (9%), Hispanic (9%), other (3%) **Other sample characteristics:** 41% married/cohabiting, average of 14.7 yrs education

Litt 2010 *(Continued)*

Interventions	• CBT • Usual care
Outcomes	• MPI • Center for Epidemiological Studies Depression Scale • SCL-90 somatisation scale • Adverse events Used in study but not review: • Pain Stages of Change questionnaire • Pain-related Self Statements Scale • Chronic Pain Self-efficacy Scale • Miller Behavioural Style Scale
Identification	**Date of study:** October 2003 to July 2007, published 2009 to 2010 **Sponsorship source:** "Support for this project was provided by grants R01-DE14607from the National Institute on Dental and Craniofacial Research and by General Clinical Research Center grant M01-RR06192 from the National Institutes of Health." **Setting:** dental hospital - university school of dental medicine **Country:** USA **Author name:** Mark D Litt **Institution:** University of Conneticut **Email:** Litt@nso.uchc.edu **Address:** Division of Behavioral Sciences and Community Health – MC3910, University of Connecticut Health Center, Farmington, CT 06030, USA
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Stratified randomisation (computerised urn method) generated by an independent study co-ordinator
Allocation concealment (selection bias)	High risk	Not discussed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for participants to be blinded to treatment in this type of trial. Study personnel were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors not blinded as participant self-report
Incomplete outcome data (attrition bias) All outcomes	Low risk	"At posttreatment 88% of patients provided data, and 73% provided data at 52 weeks. Losses to follow-up were equivalent across treatment conditions."

Litt 2010 *(Continued)*

		"Analysis of main effects of treatment on each of the three major dependent variables was conducted using a mixed model regression procedure (Proc MIXED, SAS Institute [25]), and an intent-to-treat approach."
Selective reporting (reporting bias)	Low risk	Model for mediators and moderators is well described and tested. Plausible outcome data are presented.
Other bias	Low risk	None noted

Lupton 1968

Study characteristics	
Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 2
Participants	**Inclusion criteria:** not reported **Exclusion criteria:** not reported **Pretreatment:** no **Number eligible for study:** not reported **Number of participants:** 60 **Number randomly assigned to intervention (control):** 20, 20 (20) **Number started treatment in intervention (control):** 20, 20 (20) **Number completed treatment in intervention (control):** not stated **Number included in analysis from intervention (control):** not stated **Comorbidity:** not reported **Sex:** 49 female, 11 male **Ethnicity:** white (52) **Other sample characteristics:** median level of education = 12th grade, married, median age = 30 years, dominant category of personality diagnosis
Interventions	• Counselling (advice) • Instruction (education) • Dental management
Outcomes	Used in study but not review: • Dentist-rated TMJ dysfunction rating • MMPI • Personality variables
Identification	**Date of study:** not reported **Sponsorship source:** not reported

Lupton 1968 *(Continued)*

	Setting: TMJ Research Center of the College of Dentistry of the University of Illinois **Country:** USA **Author name:** Daniel E Lupton **Institution:** University of Ilinois **Email:** none **Address:** University of Ilinois
Notes	Data extraction not completed as outcomes relevant to the review are not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Method not reported
Allocation concealment (selection bias)	High risk	Not concealed
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	Main outcome is the subjective opinion of the treating dentist.
Incomplete outcome data (attrition bias) All outcomes	High risk	No information about how many participants completed treatment or were included in the analysis.
Selective reporting (reporting bias)	Low risk	All outcomes measured appear to be reported.
Other bias	High risk	Main outcome measure is a subjective judgement by the treating dentist; author of the report also served as tutor/counsellor in both groups.

Mishra 2000

Study characteristics

Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 3
Participants	**Inclusion criteria:** participants must have endorsed past or present jaw or facial pain, clicking, popping, or locking of the jaw or have received a past diagnosis of TMD

Mishra 2000 *(Continued)*

Exclusion criteria: significant physical health condition (e.g. cancer, multiple sclerosis, carpal tunnel syndrome, fibromyalgia); 6 or more DSM-IV Axis I diagnoses, psychosis, or active suicidal ideation; score 15 or below on the CPI (considered "doing well" and not in need of treatment)

Pretreatment: no significant group differences at intake

Number eligible for study: not stated

Number of participants: 94

Number randomly assigned to intervention (control): 22, 23, 24 (25)

Number started treatment in intervention (control): not stated

Number completed treatment in intervention (control): 22, 23, 24 (25)

Number included in analysis from intervention (control): 22, 23, 24 (25)

Comorbidity: people with significant comorbidities including cancer and other pain conditions excluded, otherwise not mentioned

Sex: 77 female, 17 male

Ethnicity: white 74, African-American 8, Hispanic 10, other 2

Other sample characteristics: mean education 15.54 years

Interventions

- Cognitive behavioural skills
- Biofeedback
- Combined
- No treatment control

Outcomes

- Characteristic Pain Intensity
- POMS total mood disturbance also split into 6 variables: tension, depression, anger, vigour, fatigue, confusion

Used in study but not review:

- GCPS
- Limitations related to mandibular functioning

Identification

Date of study: paper published 2000

Sponsorship source: grants ROI DE10713 and K02 MH01107 National Institutes of Health

Setting: university clinic

Country: USA

Author name: Kiran Mishra

Institution: University of Texas

Email: robert.gatchel@email.swmed.ed

Mishra 2000 *(Continued)*

	Address: Department of Psychiatry, Division of Psychology, The University of Texas Southwestern Medical Center at Dallas, 5323 Harry Hines Boulevard, Dallas, Texas 75235-9044.
Notes	Includes Mishra 2000, Gardea 2001 and Bernstein 2000. There are some discrepancies in methods reported between these papers.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Stratified randomisation (urn method) of randomisation
Allocation concealment (selection bias)	High risk	Allocation concealment not discussed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants in this kind of study. No mention of blinding of personnel
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report; participants as own outcome assessors. No mention of blinding of study assessors
Incomplete outcome data (attrition bias) All outcomes	High risk	Number of participants who provided outcome data is not stated. Differences between papers of the same study in number of participants included, Mishra 2000 states 94, Gardea 2001 states 108, Bernstein 2000 states 121.
Selective reporting (reporting bias)	High risk	Measures described include pain, disability and mood, which are primary outcomes for this kind of study. Inconsistency in results, for example, CPI pre- and post-treatment scores reported but POMS change scores for each scale reported.
Other bias	Low risk	None noted

Mora 2013

Study characteristics

Methods	**Study design:** parallel-group RCT **Date of study:** August 2008 to April 2011 **Setting of intervention:** university - Marburg Dental School **Number of separate groups included in the study:** 2 **Number of control groups:** 1 **Number of intervention groups:** 1
Participants	**Inclusion criteria:** painful axis 1 TMD diagnosis according to the RDC/TMD diagnostic criteria. Pain present for at least 3 months. Age between 18 and 70 **Exclusion criteria:** patient already has an occlusal appliance, needs further diagnostic investigation or dental or maxillofacial treatment as judged by a specialised dentist, has other major chronic pain con-

Mora 2013 *(Continued)*

	ditions predominant in disability such as chronic low back pain or headache, has major medical or psychiatric conditions that would interfere with the ability to participate, has no pain **Eligible for study**: 70 **Total participants**: 58 **Randomly assigned to intervention** (control): 29 (29) **Started treatment in intervention** (control): 29 (27) **Completed treatment in intervention** (control): 27 (27) **Included in analysis from intervention** (control): 29 (27) **Pretreatment:** no significant group differences at intake **Comorbidity:** pain comorbidities excluded **Sex:** not reported **Ethnicity:** not reported **Other:** seeking treatment at a university dental clinic; TMD diagnosis based on RDC for TMD
Interventions	**Intervention characteristics** • Biofeedback-based CBT (BFB-CBT) • Dental treatment with occlusal splint • 8 weekly sessions of either treatment BFB-CBT or 8 weeks of occlusal splint treatment
Outcomes	Primary • Pain intensity - Characteristic Pain Intensity • Pain disability - Pain Disability Index • Adverse events • Psychological distress - CES-D • Quality of life • Additional physical symptoms (by checklist) SOMS-7 (Screening for Somatoform Symptoms) Secondary • Emotional functioning • Pain coping, somatoform symptoms • Treatment satisfaction • Number of Masseter Muscle Activity was assessed during 3 nights pretreatment and post-treatment with portable devices. Follow-up assessment took place 6 months after the treatment. Used in study but not review: • Jaw disability list • GAD-7 for anxiety • Patient Global Impression of Change Scale • Satisfaction with treatment • German pain coping questionnaire (FESV) • Pain VAS rating scale average of 3 scales
Identification	**Sponsorship source:** none stated **Country:** Germany

Mora 2013 *(Continued)*

	Setting: specialist dental clinic at a university **Author name:** Meike C Shedden Mora **Institution:** Marburg University **Email:** m.shedden@staff.uni-marburg.de **Address:** Department of Clinical Psychology and Psychotherapy, Philipps University of Marburg, Gutenbergstr. 18, 35032 Marburg, Germany
Notes	Emailed Cochrane Oral Health on 29 April 2020 to request a translation or help with data extraction as article is written in German. Data summary provided.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random assignment to conditions was generated by a researcher not involved in the study, with the use of randomisation software (GraphPad Software Inc. La Jolla, CA).
Allocation concealment (selection bias)	Low risk	Assignment was concealed in closed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not possible for participants. Personnel blinded as far as possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors were blind to treatment status.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention-to-treat analysis
Selective reporting (reporting bias)	Low risk	Outcomes are reported as described in the methods.
Other bias	Low risk	None identified

NCT00066937

Study characteristics

Methods	**Study design:** parallel-group RCT **Number of control groups:** 2 **Number of intervention groups:** 2
Participants	**Included criteria:** age 18 to 65 years, pain of at least 3 months duration due to TMD, pain due to TMD is primary if other pain conditions present **Excluded criteria:** continuous, chronic painful non-reducing disc displacement of TMJ and patient cannot open mouth, unstable or acute severe pain from another pain condition, pregnancy, presence

NCT00066937 *(Continued)*

	of a medical condition that contraindicates nortriptyline: angle-closure glaucoma, symptomatic orthosis, electrocardiogram: first degree heart block or QTc > 450 msec, unstable angina or a history of a myocardial infarction within the past 3 months, current treatment with an antidepressant that cannot be withdrawn, current use of a medication that interacts with nortriptyline to raise blood levels, such as selective serotonin reuptake inhibitors (e.g. paroxetine), systemic antifungal agents (fluconazole), antiarrhythmics (e.g. quinidine), antipsychotics (e.g. haloperidol) and antibiotics (e.g. erythromycin), presence of dementia, psychosis or other disorder of cognition that impairs ability to participate in minimal contact intervention, BDI score ≥ 35 or BDI Item #9 (suicide item) is scored > 1, terminal illness with a life expectancy of less than 6 months, history of arthrotomy of TMJ, history of allergic reaction to nortriptyline or benztropine, history of a therapeutic trial with nortriptyline (dose ≥ 100 mg for at least 3 weeks) **Pretreatment:** unclear **Number eligible for study:** not stated **Number of participants:** 140 **Number randomly assigned to intervention (control):** nortriptyline plus CBT 41, nortriptyline plus disease management 37, benztropine (placebo) plus CBT 38, benztropine (placebo) plus disease management 24 **Number started treatment in intervention (control):** 41 (38) **Number completed treatment in intervention (control):** nortriptyline plus CBT 38, nortriptyline plus disease management 26, benztropine (placebo) plus CBT 33, benztropine (placebo) plus disease management 19 **Number included in analysis from intervention (control):** nortriptyline plus CBT 38, nortriptyline plus disease management 33, benztropine (placebo) plus CBT 26, benztropine (placebo) plus disease management 19 **Comorbidity:** not stated **Sex:** 105 female, 35 male **Ethnicity:** not stated **Other sample characteristics:** n/a
Interventions	• Nortriptyline plus CBT • Active placebo (benztropine) plus CBT • Disease management plus nortriptyline • Disease management plus active placebo (benztropine)
Outcomes	• Pain intensity - average pain on 10-point scale where 0 is no pain and 10 is worst pain • Adverse events - collected weekly • Psychological distress: SF-36 (Short Form-36) Measured at baseline, post-treatment, 3 months, 6 months Used in study but not review: • Change in pain-related interference • Worst pain on 10-point scale
Identification	**Date of study:** November 2002 to June 2008, data reported 2017 **Sponsorship source:** National Institute of Dental and Craniofacial research **Country:** USA **Setting:** university

NCT00066937 *(Continued)*

Author name: Jennifer A Haythornthwaite

Institution: University of Maryland

Email: not known

Address: University of Maryland, Dental School, Baltimore, Maryland, United States, 21201

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"factorial assignment"
Allocation concealment (selection bias)	Unclear risk	Registry does not provide sufficient detail for a judgement
Blinding of participants and personnel (performance bias) All outcomes	High risk	States fourfold blinding but not enough information. Blinding of clinician not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	States outcome assessors blinded but not enough information - self-report
Incomplete outcome data (attrition bias) All outcomes	High risk	Analyses are not on intention-to treat basis, significant dropout
Selective reporting (reporting bias)	High risk	Measures seem unusual and inconsistent, e.g. average pain versus change in pain-related interference.
Other bias	High risk	Registered trial that was not published and therefore has not been peer-reviewed. Very long timescale. Study data appear to have been collected over a long period of time.

Shevtsova 2020

Study characteristics

Methods	**Study design:** RCT **Number of control groups:** 1 **Number of intervention groups:** 1
Participants	**Inclusion criteria:** people with myofascial pain syndrome who attended the pain clinic **Exclusion criteria:** not stated **Pretreatment:** not reported **Number eligible for study:** not reported **Number of participants:** 64 people who reported TMD

Shevtsova 2020 *(Continued)*

	Number randomly assigned to intervention (control): 32 **Number started treatment in intervention (control):** 32 **Number completed treatment in intervention (control):** 32 **Number included in analysis from intervention (control):** 32 **Comorbidity:** not reported **Sex:** not reported **Ethnicity:** not reported **Other sample characteristics:** not reported
Interventions	• Mindfulness (8-week course) plus medication • Medication
Outcomes	• Pain intensity on a VAS at 6 and 12 weeks after treatment
Identification	**Date of study:** not reported **Sponsorship source:** not reported **Setting:** not reported **Country:** Russia **Author name:** G Shevtsova **Institution:** The State Education Institution of HIgher Professional Training, The First Sechenov Moscow State Medical University under Ministry of Health of the Russian Federation **Email:** not reported **Address:** 8-2, Trubetskaya Street, Moscow, 119992
Notes	Conference presentation: abstract only available Limited information provided

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sealed envelopes
Allocation concealment (selection bias)	Low risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-report; not possible

Shevtsova 2020 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Not stated
Selective reporting (reporting bias)	Unclear risk	Not enough information
Other bias	Unclear risk	Not enough information

Stam 1984

Study characteristics	
Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 2
Participants	**Inclusion criteria:** diagnosed as suffering from TMPDS on the basis of lack of changes or organic disease of either TMJ as determined by radiographs, lack of tenderness of the condyles on physical examination, and presence of at least one of the following symptoms: pain and tenderness of the muscles of mastication, sounds during condylar movements, mainly clicking, and limitations of mandibular movements **Exclusion criteria:** not reported **Pretreatment:** not discussed **Number eligible for study:** not reported **Number of participants:** 61 **Number randomly assigned to intervention (control):** not reported **Number started treatment in intervention (control):** not reported **Number completed treatment in intervention (control):** 12 hypnosis, 15 relaxation (10 waiting-list control). **Number included in analysis from intervention (control):** 12, 15 (10) **Comorbidity:** not discussed **Sex:** 51 female, 10 male **Ethnicity:** not reported **Other sample characteristics:** participants ranged in age from 15 to 41 years. Mean duration of pain before treatment was 23 months (standard deviation = 26); median duration was 12 months.
Interventions	• Hypnosis • Relaxation • Waiting-list control
Outcomes	• Daily pain logs. Assessment by dental surgeon blind to treatment allocation: worse, same, improved or completely alleviated
Identification	**Date of study:** paper published 1984

Stam 1984 *(Continued)*

	Sponsorship source: not reported
	Country: Canada
	Setting: dental hospital clinic, Department of Oral Medicine
	Author name: Henderikus J Stam
	Institution: University of Western Ontario, London, Ontario, Canada
	Email: n/a
	Address: Department of Psychology, University of Calgary, Calgary, Alberta, Canada T2N 1N
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "After their pretest session, patients were randomly assigned to one of three treatments with the exception that each group had approximately equivalent numbers of subjects with high, medium, and low susceptibility to hypnosis: hypnosis (n = 12), relaxation (n = 15), or waiting-list control (WCL) (n = 14)."
Allocation concealment (selection bias)	High risk	Not discussed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind for this kind of study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-report ratings cannot be blinded. Outcome assessor who gave judgement about improvement was blind to what treatment participants had received.
Incomplete outcome data (attrition bias) All outcomes	High risk	Does not state whether intention-to-treat analysis was carried out. All participants completed daily pain ratings but results of these were only presented for 10 waiting-list control participants. At end of treatment only dentist judgements of improvement were presented.
Selective reporting (reporting bias)	High risk	Outcomes appear to have been decided once data collected.
Other bias	High risk	Subjective judgement of dentist regarding whether or not participants had improved.

Townsend 2001

Study characteristics

Methods	**Study design:** parallel-group RCT
	Number of control groups: 1
	Number of intervention groups: 1

Townsend 2001 *(Continued)*

Participants	**Inclusion criteria:** positive screen for TMD using self-report format adapted from TMD criteria outlined by AAOP 1996 and Bush 1995. The criteria include a report of pain in the TMJ or surrounding musculature in the past year (a) locked jaw; (b) mandibular joint sounds; (c) stiffness, tenderness, or tightness in the jaw; (d) pain in the ears, temple or cheek; or (e) uncomfortable bite. **Exclusion criteria:** (a) having had head or facial surgery, (b) diagnosis of degenerative joint disorder, (c) currently taking psychotropic medication, or (d) pregnancy **Pretreatment:** at baseline, the control group reported higher educational level than the treatment group. No other significant differences **Number eligible for study:** 24 **Number of participants:** 20 **Number randomly assigned to intervention (control):** not stated **Number started treatment in intervention (control):** 10 (10) **Number completed treatment in intervention (control):** not exactly clear as article states 10 (10), but also mentions imputation of data using the last available score **Number included in analysis from intervention (control):** 10 (10) **Comorbidity:** not discussed **Sex:** all female **Ethnicity:** all white **Other sample characteristics:** 100% employed full time, none receiving non-pharmacological treatment, 80% reported use of intra-oral appliance
Interventions	• Habit reversal treatment • Waiting-list control

Outcomes	• MPI
	
	Used in study but not review:
	
	• Facial pain diary filled in 4 x day from which derived:
	  ◦ mean weekly pain rating
	  ◦ mean number pain-free days
	  ◦ highest pain intensity rating for the week
	• Oral habits questionnaire
	• Hassles Scale
	• Global perceptions of functioning post-treatment

Identification	**Date of study:** published 2001, recruitment over 15-month period **Sponsorship source:** none - student dissertation **Country:** USA **Setting:** not stated. Minimal contact so mainly in participants' homes, intake probably in university psychology department **Author name:** Donald Townsend **Institution:** Virginia Commonwealth University **Email:** corresponding author: sgramlin@mail1.vcu.edu

Townsend 2001 *(Continued)*

	Address: Metropolitan Sleep Disorders Center, St. Paul, MN, USA; Department of Psychology, Virginia Commonwealth University, Box 2018, Richmond, VA, USA
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Blocked randomisation table with numbers to represent each treatment condition. Partially randomised as participants who dropped out prior to treatment were replaced by the next available person. The advanced student who also acted as therapist and researcher performed the randomisation.
Allocation concealment (selection bias)	High risk	Group therapist assigned numbers on the block randomisation to participants after conducting a pre-treatment assessment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants to this kind of study. Study personnel aware of treatment allocation.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report; participants as own outcome assessors; no information about who processed the outcome data.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "the fact that information is only available for those who completed the study (thus not allowing for the preferred ‘‘intent-to-treat’’ analysis) should give pause to overgeneralization of the current findings." Comment: information is not presented clearly about treatment dropout.
Selective reporting (reporting bias)	Low risk	Primary outcomes of interest to the review are reported.
Other bias	Low risk	None noted

Turk 1993

Study characteristics

Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 2
Participants	**Inclusion criteria:** pain and tenderness of the muscles of mastication and TMJ region and limited mandibular movements of 2 months duration or longer, no evidence of serious psychopathology, no history of TMJ-related surgery, and at least 18 years of age **Exclusion criteria:** not specified **Pretreatment:** none **Number eligible for study:** not stated **Number of participants:** 80

Turk 1993 *(Continued)*

	Number randomly assigned to intervention (control): 30, 30 (20) **Number started treatment in intervention (control):** not stated **Number completed treatment in intervention (control):** not stated **Number included in analysis from intervention (control):** not stated **Comorbidity:** not reported **Sex:** not reported **Ethnicity:** not reported **Other sample characteristics:** n/a
Interventions	• Intraoral appliance • Biofeedback/stress management • Waiting-list control • Combined intraoral appliance, biofeedback, stress management
Outcomes	• Pain intensity - PSS (pain severity scale) from MPI • Psychological distress - CES-D, POMS, BDI, Affective Distress Scale
Identification	**Date of study:** paper published 1993 **Sponsorship source:** USPHS Research Grant ROl DE07514 from the NIDR, National Institutes of Health **Country:** USA **Setting:** university clinic **Comments:** data from study 2 (combined group) not included in data synthesis as this part of the trial was not randomised **Author name:** Dennis C Turk **Institution:** University of Pittsburgh **Email:** none provided **Address:** Department of Psychiatry; Director of Pain Evaluation and Treatment Institute, University of Pittsburgh School of Medicine
Notes	This paper reports on 2 studies; participants in study 1 were randomised, but in study 2 the next 30 consecutive patients referred for treatment composed the study group. Only study 1 is included in the review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Sequence generation not discussed
Allocation concealment (selection bias)	High risk	Allocation concealment not discussed
Blinding of participants and personnel (performance bias)	High risk	No discussion of blinding. Blinding is not possible for this type of intervention.

Turk 1993 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of outcome assessors not discussed
Incomplete outcome data (attrition bias) All outcomes	Low risk	Treatment dropout is low, although no intention-to-treat analysis
Selective reporting (reporting bias)	Low risk	Data are reported for all measures described in the methods.
Other bias	Low risk	None noted

Turk 1996

Study characteristics	
Methods	**Study design:** parallel-group RCT **Number of control groups:** 1 **Number of intervention groups:** 1
Participants	**Inclusion criteria:** pain and tenderness of the muscles of mastication and TMI region and restricted mandibular opening of 3 months duration or longer, no evidence of serious psychopathology, no history of TMJ-related surgeries and at least 18 years of age **Exclusion criteria:** not explicitly stated. None of the participants were receiving disability payments in relation to their pain. **Pretreatment:** no significant differences between groups at baseline. **Number eligible for study:** not stated **Number of participants:** 48 **Number randomly assigned to intervention (control):** 24 (24) **Number started treatment in intervention (control):** 24 (24) **Number completed treatment in intervention (control):** 22 (23) **Number included in analysis from intervention (control):** 21 (20) **Comorbidity:** not reported **Sex:** 90% female, 10% male **Ethnicity:** not reported **Other sample characteristics:** high school graduation 92%, single 25%, married 68%, separated/divorced 7%, full-time employment 61%
Interventions	• Splint plus stress management plus cognitive therapy (for depression) • Splint plus stress management plus nondirective counselling
Outcomes	• Pain intensity: McGill Pain Inventory • Pain disability: Interference Scale from MPI

Turk 1996 *(Continued)*

	• Psychological distress: BDI Used in study but not review: • Pain Catastrophizing Scale from Coping Strategies questionnaire
Identification	**Date of study:** published 1996 **Sponsorship source:** US Public Health Service Research Grant R01 DE07514 from the NIDR, National Institutes of Health **Country:** USA **Setting:** University of Pittsburgh Medical Centre **Author name:** Dennis C Turk **Institution:** University of Pittsburgh **Email:** not reported **Address:** Dennis C Turk, Pain Evaluation and Treatment Institute, University of Pittsburgh Medical Center, 4601 Banm Boulevard, Pittsburgh, Pennsylvania 15213
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Method of sequence generation not discussed
Allocation concealment (selection bias)	High risk	Allocation concealment not discussed. Participants were all allocated to an active treatment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not discussed. Blinding of participants and treatment providers not possible for this kind of study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-report - participants as own outcome assessors. Blinding of study assessors not discussed
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low dropout, although does not use intention-to-treat analyses. 22 and 23 out of 24 completed the treatment and 21 and 22 reached 3-month follow-up
Selective reporting (reporting bias)	Low risk	Outcomes appear to be comprehensively reported, including core outcomes of pain and interference.
Other bias	Low risk	None noted

Turner 2006

Study characteristics

Methods	**Study design:** parallel-group RCT

Turner 2006 *(Continued)*

Number of control groups: 1

Number of intervention groups: 1

Participants	**Inclusion criteria:** age 18 years or older, RDC/TMD Axis I TMD diagnosis Dworkin 1992 made by an oral medicine specialist based on a structured RDC/TMD clinical examination, residence within a 2-hour drive of the TMD clinic, facial pain for at least 3 months, facial pain-related disability, as defined by a chronic pain grade of II high, III, or IV (Von Korff 1992) and ability to communicate in English **Exclusion criteria:** need for further diagnostic evaluation, pending litigation or disability compensation for pain, current or previous CBT for pain, and major medical or psychiatric conditions that would interfere with ability to participate **Pretreatment:** similar demographically at baseline. More self-care patients had disc displacement and more participants in PMT group had osteoarthritis of the jaw joint. **Number eligible for study:** 366 **Number of participants:** 158 **Number randomly assigned to intervention (control):** 79 (79) **Number started treatment in intervention (control):** 77 (79) **Number completed treatment in intervention (control):** 57 (53) completed all sessions, 67 (69) completed some sessions **Number included in analysis from intervention (control):** 72 (76) **Comorbidity:** not discussed **Sex:** 86% female, 14% male **Ethnicity:** 84% white **Other sample characteristics:** referred to specialist clinic
Interventions	• CBT (PMT) • Self-care management (SCM) (control)
Outcomes	• Characteristic Pain Intensity • BDI Used in study but not review: • GCPS category • Mandibular Function Impairment Questionnaire • Process measures: Survey of Pain Attitudes, TMD self-efficacy scale, Coping Strategies Questionnaire catastrophising scale, Pain Catastrophizing Questionnaire, Chronic Pain Coping inventory
Identification	**Date of study:** 2001 to 2004, paper published 2006 **Sponsorship source:** funding for this study was provided by the National Institute of Dental and Craniofacial Research Grant P01 DE08773 **Country:** USA

Turner 2006 *(Continued)*

	Setting: Specialist Orofacial Pain Clinic
	Author name: Judith A Turner
	Institution: University of Washington
	Email: jturner@u.washington.edu
	Address: Department of Psychiatry and Behavioral Sciences, University of Washington School of Medicine, Seattle, WA, USA
Notes	One of the three papers relating to this study was additional analyses of mediators and moderators, but had no additional raw data (Turner 2007).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Generated by a biostatistician on a computer programme using stratified sampling in random block designs
Allocation concealment (selection bias)	Low risk	Sequentially numbered envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants due to nature of study. Randomsation assignment was concealed to all study personnel until envelopes were opened by research staff after participant consent was obtained.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of outcome assessors not mentioned. Self-report so participants largely acting as their own outcome assessors and cannot be blind to the treatment they have received.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Clear rationale of imputation and sensitivity analyses where intention-to-treat analysis not possible due to dropout
Selective reporting (reporting bias)	Low risk	Predetermined endpoints for analysis. Table reports data for all key measures collected.
Other bias	Low risk	None noted

Turner 2011

Study characteristics

Methods	**Study design:** parallel-group RCT
	How many control groups: 1
	How many intervention groups: 2
Participants	**Inclusion criteria:** female, age 18 to 45 years, premenopausal, RDC/TMD Axis I TMD pain diagnosis made by an oral medicine specialist based on a structured RDC/TMD clinical examination, characteristic pain intensity ≥ 3 (0 to 10 scale, past 6 months timeframe), ability to communicate in English
	Exclusion criteria: lacking menstrual cycle, pregnant, lactating, planning to become pregnant in next 7 months, unwilling to take a continuous oral contraceptive, need for further diagnostic evaluation of fa-

Turner 2011 *(Continued)*

	cial pain (determined by oral medicine specialist), major medical/psychiatric comorbidities that would interfere with ability to participate, medical contraindication for continuous oral contraceptive therapy, smoked and ≥ 35 years old, used medication in last 3 months that interfered with oestrogen or progestin metabolism, abnormal pelvic exam abnormal pap smear, undiagnosed uterine bleeding, no current mammogram and ≥ 40 years old **Pretreatment:** targeted self-management therapy group significantly younger, although all groups' average age 25 to 29. No other significant differences between groups. **Number eligible for study:** 570 **Number of participants:** 191 **Number randomly assigned to intervention (control):** 60 (57) (74) **Number started treatment in intervention (control):** (55) (52) (36) **Number completed treatment in intervention (control):** self-management therapy 54 (completed at least 1 session), targeted self-management therapy 50, continuous oral contraceptive therapy 36 **Number included in analysis from intervention (control):** (51) (47) (49) **Comorbidity:** none specified **Sex:** all female **Ethnicity:** 78% white non-Hispanic **Other sample characteristics:** menstruating
Interventions	• Self-management therapy • Targeted self-management therapy • Continuous oral contraceptive therapy
Outcomes	• Characteristic Pain Intensity • BDI Used in study but not review: • GCPS • Clinically-meaningful improvement in pain • McGill Pain Questionnaire • Adverse Effects
Identification	**Date of study:** recruitment occurred between 2005 and 2009, paper published 2011 **Sponsorship source:** National Institute of Dental and Craniofacial Research **Country:** USA **Setting:** university orofacial pain clinic **Author name:** Judith A Turner **Institution:** University of Washington **Email:** jturner@u.washington.edu **Address:** University of Washington School of Medicine, Department of Psychiatry and Behavioral Sciences, Box 356560, Seattle, WA 98195, USA
Notes	-

Turner 2011 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Stratified block randomisation undertaken by study assistant not involved in screening using a computer programme
Allocation concealment (selection bias)	Low risk	Sequence put into opaque, sequentially numbered envelopes by an assistant not otherwise involved in the study
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants to the intervention received in this type of trial. Study assistant was blinded. All study personnel remained blind to assignment until the point of randomisation.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not possible to blind for self-report outcome questionnaires. Blinding of outcome assessors is not explicitly reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data clearly described and sensitivity analysis carried out regarding imputation and intention-to-treat strategy.
Selective reporting (reporting bias)	Unclear risk	Pain is primary outcome; pain interference and BDI also core outcomes for this population so good coverage; however, many questionnaires used and not all are reported in detail
Other bias	Low risk	None noted

Wahlund 2003

Study characteristics

Methods	**Study design:** parallel-group RCT **How many control groups:** 2 (occlusal appliance designated by review author as control group) **How many intervention groups:** 1
Participants	**Inclusion criteria:** TMD diagnosis according to RDC/TMD, reported pain once a week or more for 3 months in jaw, face or temples. Age 12 to 18 years **Exclusion criteria:** juvenile rheumatoid arthritis, migraine, current treatment with orthodontic appliances that could interfere with treatment **Pretreatment:** groups seem to be relatively similar; more females than males, which reflects the population with TMD **Number eligible for study:** not stated **Number of participants:** 122 **Number randomly assigned to intervention (control):** relaxation 41, oral appliance 42 (39) **Number started treatment in intervention (control):** 41, 42 (39) **Number completed treatment in intervention (control):** 34, 37 (39) **Number included in analysis from intervention (control):** 34, 37 (39)

Wahlund 2003 *(Continued)*

	Comorbidity: see exclusion criteria above **Sex:** 93 female, 29 male **Ethnicity:** not reported **Other sample characteristics:** n/a
Interventions	• Relaxation plus brief information • Active control (oral appliance) plus brief information • Brief information only
Outcomes	• Pain index (composite measure of intensity x frequency) Used in study but not review: • Pain intensity (NRS) • Pain frequency (NRS) • Pain diary (4 x day, total weekly score 1 to 140) • 50% improvement in pain • Analgesic use • School absence • Subjective evaluation of treatment (6-point scale: completely well to much worse)
Identification	**Date of study:** 2003. Data from 1996 to 2000 **Sponsorship source:** Public Dental Service of Ostergotland **Country:** Sweden **Setting:** specialist TMD clinic **Author name:** Kerstin Wahlund **Institution:** TMD Unit, Specialist Center for Oral Rehabilitation, LinkoÈping, Sweden **Email:** kerstin.Wahlund@lio.se **Address:** TMD Unit, Specialist Center for Oral Rehabilitation, Torkelbergsgatan 11, SE-581 85 LinkoÈping, Sweden. Tel. +46 13 228850, fax. +46 13 228847.
Notes	-

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	No mention of randomisation process
Allocation concealment (selection bias)	High risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel not blinded but unable to do this in this study design
Blinding of outcome assessment (detection bias)	Low risk	Examiner was blind to treatment allocation. Self-report measures.

Wahlund 2003 *(Continued)*

All outcomes		At each evaluation all subjects filled out a self-administered questionnaire and were clinically examined by a 'blinded' calibrated clinician.
Incomplete outcome data (attrition bias) All outcomes	High risk	12% dropout, which was comparable between groups. Analysis was on the basis of treatment completers. Despite reporting of dropouts, appears > 10% in both intervention groups dropped out and were not included in analysis.
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods are reported.
Other bias	Low risk	None noted

Wahlund 2015

Study characteristics	
Methods	**Study design:** parallel-group RCT (cross-over study considered as parallel group as only first period data used)
Participants	**Inclusion criteria:** age 12 to 19 years, TMD pain at least once a week for 3 months, RDC/TMD diagnosis of myofascial pain, seeking treatment **Exclusion criteria:** myofascial diagnosis or other diagnosis such as juvenile idiopathic arthritis or migraine, receiving orthodontic treatment that might interfere with treatment **Pretreatment:** no significant differences at baseline **Number eligible for study:** 111 **Number of participants:** 64 **Number randomly assigned to intervention (control):** 31 (33) **Number started treatment in intervention (control):** 30 (29) **Number completed treatment in intervention (control):** 28 (29) **Number included in analysis from intervention (control):** 28 (29) **Comorbidity:** not stated **Sex:** 61 female, 3 male **Ethnicity:** not reported **Other sample characteristics:** n/a
Interventions	• Relaxation: 8 sessions of relaxation training 45 minutes (total 6 hours) with manual, compact disc and expectation to practice daily • Oral appliance active control: fitted oral appliance
Outcomes	• Pain index (mean of two 11-point scales reporting pain intensity and pain frequency) (lower is better) Used in study but not review: • Pain intensity (NRS) • Pain frequency (NRS) • Pain unpleasantness • Pain diary (4 x day, total weekly score 1 to 140)

Wahlund 2015 *(Continued)*

- 50% improvement in pain
- Analgesic use
- School absence
- Subjective improvement (Patient Global Impression of Change scale)

Identification	**Date of study:** published 2015. Study conducted between September 2003 and January 2011 **Sponsorship source:** The Swedish Dental Society, The Public Dental Service of Ostergotland, Public Dental Service of Kalmar **Country:** Sweden **Setting:** specialist dental settings for TMD pain **Author name:** Kerstin Wahlund **Institution:** TMD Unit, Specialist Center for Oral Rehabilitation, LinkoÈping, Sweden **Email:** Kerstin.Wahlund@ltkalmar.se **Address:** Senior Consultant, Department of Stomatognathic Physiology, Kalmar County Hospital, Kalmar, Sweden
Notes	Pain index only partially reported This is reported as a cross-over study, but we have only considered the first part of the study, which was designed as a standard RCT comparing relaxation and occlusal appliance. Longest follow-up was 6 months and included only people who were satisfied with current pain and therefore did not wish to go into the cross-over trial of the occlusal appliance. Data not suitable for combining in a meta-analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sequences generated from a random number table and put in opaque envelopes Quote: "random number table, a secretary not otherwise involved in the study generated the allocation sequence to assign patients to a treatment, either OA or RT."
Allocation concealment (selection bias)	Low risk	Secretary otherwise not involved in the study used the random number table and put assigned numbers into opaque envelopes. Envelopes were opened by a trained nurse after gathering patient information.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for participants, healthcare workers providing interventions, and other personnel
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded. Quote: "Two previously calibrated TMD specialists (KW and IMN), blinded to group assignment, performed the examination."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Dropout rates similar between groups: 3 (9.7%) in relaxation therapy and 4 (12.1%) with oral appliance. Dropouts excluded from data analysis but we found similar results with intention-to-treat analysis using imputations.

Wahlund 2015 *(Continued)*

Selective reporting (reporting bias)	Low risk	All outcomes described in the methods are reported in the results.
Other bias	Low risk	None noted

BDI: Beck Depression Inventory; CBT: cognitive behaviour therapy; CES-D: Centre for Epidemiological Studies in Depression; DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, fourth edition; GAD-7: General Anxiety Disorder 7-item questionnaire; GCPS: Graded Chronic Pain Scale; MMPI: Minnesota Multiphasic Personality Inventory; MPI: Multidimensional Pain Inventory; n/a: not applicable; NIDR: National Institute of Dental Research; NRS: numerical rating scale; OA: occlusal appliance; PMT: pain management training; POMS: Profile of Mood States; RCT: randomised controlled trial; RDC: research diagnostic criteria; RT: relaxation therapy; SCL: symptom checklist; TMD: temporomandibular disorder; TMJ: temporomandibular joint; TMPDS: temporomandibular pain and dysfunction syndrome; VAS: visual analogue scale; USPHS: United States Public Health Service; WHYMPI: West Haven-Yale Multidimensional Pain Inventory

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Carlson 2001	Does not fit our criteria for psychological intervention.
Conti 2015	Does not fit our criteria for psychological intervention.
Crockett 1986	Does not fit our criteria for psychological intervention.
de Resende 2019	Does not fit our criteria for psychological intervention.
Ferrando 2012b	Full text not available
Flor 1993	Data were not presented separately for participants with TMD.
Funch 1984	Does not fit our criteria for psychological intervention.
Halmova 2017	Does not fit our criteria for psychological intervention.
Huhtela 2019	Does not fit our criteria for psychological intervention.
Lam 2020	Does not fit our criteria for psychological intervention.
Litt 2013	Conference proceedings - not enough information
Manfredini 2017	Does not fit our criteria for psychological intervention.
Massouth 1992	Conference proceedings - not enough information
Melo 2020	Does not fit our criteria for psychological intervention.
Michelotti 2002	Does not fit our criteria for psychological intervention.
Ommerborn 2007	Participants not diagnosed with TMD.
Pfeil 1987	Full text not available
Takeuchi Sato 2019	Does not fit our criteria for psychological intervention.
Treacy 1999	Participants not diagnosed with TMD.

Study	Reason for exclusion
van Grootel 2017	Does not fit our criteria for psychological intervention.

TMD: temporomandibular disorder

Characteristics of ongoing studies *[ordered by study ID]*

CTRI2007091000047

Study name	A clinical trial to study the effects of three physiotherapy treatments - jaw muscle exercise, myofascial release and cognitive behavioral therapy in temporomandibular muscle pain patients
Methods	Multi-arm parallel RCT Random sequence generation: random number table. Method of allocation concealment: sequentially numbered, sealed, opaque envelopes Blinding: outcome assessor blinded
Participants	TMJ myofascial pain syndrome: localised pain on palpation of jaw muscles, diffuse pain reproduced to head or face, pain on resisted contraction of the jaw, passive range of jaw opening is greater than active pain-free range
Interventions	• Myofascial release techniques: gross (head pull, hair pull, ear pull (each 30 s)) and focused techniques (ischaemic compression (1 min), and stretches (5 min)) • CBT: pain physiology education (5 min), stress and myofascial pain syndrome education (5 min), cortical somesthesis education (5 min) • Control: masticatory muscle re-education (5 min), active jaw muscle exercises with tongue-up position (5 min)
Outcomes	• Primary: pain-free range of jaw opening; perceived pain intensity on VAS; pressure pain threshold of masseter muscle • Secondary: Jaw Pain and Function Questionnaire All measured day 1 before treatment and day 5 after 5 treatment sessions
Starting date	1 Febuary 2008
Contact information	Senthil Kumar Paramasivam, mptmanip@yahoo.com Manipal University, India
Notes	

JPRN-C000000365

Study name	Randomized controlled clinical trial of cognitive behavioral therapy for chronic muscle pain in head, neck and shoulder regions
Methods	Parallel RCT
Participants	Target: 166 Age 16 to 55 years

JPRN-C000000365 *(Continued)*

	Inclusion criteria: age 16 to 55 years, chronic pain in masticatory muscles more than 4 weeks, pain ranked more than 4 on a VAS over 4 weeks until starting trial, able to go to hospital during the 26 weeks of the study **Exclusion criteria**: undergone treatment for TMD, pain caused by abnormal shape of bone, adhesion, disk displacement/perforation in TMJ, unable to fit splint to jaw because of missing teeth, judged by dentists not to be appropriate for this trial
Interventions	• CBT only versus CBT and stabilisation splint therapy
Outcomes	• Effective rate of VAS for pain in masticatory muscle (effective = VAS decreased more than 50% of the initial degree)
Starting date	1 March 2006
Contact information	Shoichi Ishigaki, ishigaki-s@umin.net
Notes	Sponsor: Osaka University Graduate School of Dentistry Funder: Japan Society for the Promotion of Science

NCT00067366

Study name	Brief treatment for temporomandibular pain
Methods	Open-label parallel RCT
Participants	**Inclusion criteria** • 18 to 65 years of age • Complaining of chronic TM-related pain for at least 3 months • Positive Axis I diagnosis on the Research Diagnostic Criteria (RDC) for TMDs (positive on at least one group), and may have no contraindications to TMD treatment • Fluency in English **Exclusion criteria** • No previous surgery for treatment of TMD pain • No history of rheumatoid disease • No extensive anatomical destruction or deterioration of the TMJ • Not diagnosed as having pain of neuropathic or odontogenic origin • Not carrying a diagnosis of psychosis • No current treatment for depression • Not taking narcotic pain medication • Not pregnant
Interventions	• Standard conservative treatment with an intraoral splint plus anti-inflammatory agents versus standard treatment + CBT programme 6 clinic visits in each intervention
Outcomes	• Pain: multidimensional pain ratings collected in person every 3 months • Pain-related interference with functioning: multidimensional function ratings collected in person every 3 months • Depressive symptoms: CES-D depressive symptoms scale administered in person every 3 months

NCT00067366 *(Continued)*

Starting date	October 2003
Contact information	Mark Litt, Professor, University of Connecticut Health Center, USA
Notes	

NCT00769561

Study name	Biofeedback-based cognitive behavioral treatment for temporomandibular disorders
Methods	Single-blind parallel RCT
Participants	**Inclusion criteria** • Age 18 to 70 years • Clinical diagnosis of painful temporomandibular disorder according to Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) • Symptoms persist at least 3 months • Sufficient language skills **Exclusion criteria** • Somatic diagnosis that requires defined somatic treatment (e.g. occlusal interference) • Presence of a psychotic disorder • Presence of neurological disorders (e.g. dementia) • Alcohol or substance abuse • Presence of other pain condition of predominant severity
Interventions	• Psychological intervention receiving 8 sessions of biofeedback-based CBT versus dental intervention receiving interocclusal splint therapy
Outcomes	**Primary outcome measures** • Pain intensity (German Pain Questionnaire; Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD)) • Pain disability (Pain Disability Index) • Jaw use limitations (JDL) **Secondary outcome measures** • Somatoform symptoms (Screening for Somatoform Disorders, SOMS) • Depressive symptoms (Centers for Epidemiologic Studies Depression Scale) • General anxiety symptoms (GAD-7) • Pain coping (FESV): assessed with Coping Strategies Scale from the German Pain Coping Questionnaire • TMD-related symptoms: symptoms such as jaw pain, toothache or dizziness measured using a 41-item TMD symptom list All outcomes measured pre-treatment, post-treatment after 8 weeks, and at 6-month follow-up
Starting date	August 2008
Contact information	Winfried Rief, Philipps University Marburg Medical Center
Notes	

NCT04363762

Study name	An internet-based multimodal pain program for chronic temporomandibular disorder pain
Methods	Unblinded parallel-arm RCT pilot study
Participants	**Inclusion criteria** • Age between 18 and 75 years • At least one of the TMD pain diagnoses myalgia, myofascial pain with referral, headache attributed to TMD, or arthralgia according to the DC/TMD • Chronic TMD pain (≥ 3 months), experienced once a week or more often, with an intensity of ≥ 3 on an 0 to 10 NRS • Access to a computer with an internet connection and a mobile phone • Sufficient computer literacy • Mastery of the Swedish language **Exclusion criteria** • Chronic inflammatory systemic disease • All psychiatric disorders except depression and anxiety (due to high comorbidity) • Occlusal splint therapy in the past 12 months • Ongoing extensive dental treatment • Conditions contradicting MRI examination
Interventions	Internet-based multimodal pain programme versus occlusal splint
Outcomes	Primary • Change in the Graded Chronic Pain Scale • Change in pain-related disability Secondary • Depression, assessed by the Patient Health Questionnaire-9 • Anxiety, assessed by the Generalized Anxiety Disorder-7 questionnaire • Emotonal functioning - catastrophising, assessed by Pain Catastrophizing Scale-10 • Patient Stress Scale All measured at 3 and 6 months of follow-up
Starting date	April 2016
Contact information	Professor Per Alstergren, Malmö University
Notes	

CBT: cognitive behavioural therapy; CES-D: Center for Epidemiologic Studies Depression Scale; DC/TMD: Diagnostic Criteria for Temporomandibular Disorders; MRI: magnetic resonance imaging; NRS: numeric rating scale; RCT: randomised controlled trial; TM: temporomandibular; TMJ: temporomandibular joint; TMD: temporomandibular disorder; VAS: visual analogue scale

DATA AND ANALYSES

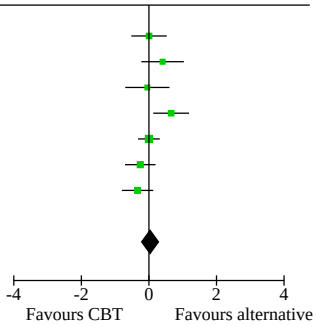
Comparison 1. CBT versus alternative active intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Pain intensity at treatment completion	5	509	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.21, 0.28]
1.2 Pain intensity at follow-up	5	475	Std. Mean Difference (IV, Random, 95% CI)	-0.29 [-0.50, -0.08]
1.3 Pain intensity at completion (sensitivity analysis structured diagnosis only)	2	276	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.33, 0.15]
1.4 Pain intensity at follow-up (sensitivity analysis structured diagnosis only)	2	290	Std. Mean Difference (IV, Random, 95% CI)	-0.45 [-0.69, -0.21]
1.5 Pain disability at treatment completion	3	245	Std. Mean Difference (IV, Random, 95% CI)	-0.15 [-0.40, 0.10]
1.6 Pain disability at follow-up	3	245	Mean Difference (IV, Random, 95% CI)	-0.15 [-0.42, 0.12]
1.7 Psychological distress at treatment completion	6	553	Std. Mean Difference (IV, Random, 95% CI)	-0.32 [-0.50, -0.15]
1.8 Psychological distress at follow-up	6	516	Std. Mean Difference (IV, Random, 95% CI)	-0.32 [-0.51, -0.13]

Analysis 1.1. Comparison 1: CBT versus alternative active intervention, Outcome 1: Pain intensity at treatment completion

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Alternative treatment Mean	Alternative treatment SD	Alternative treatment Total	Weight	Std. Mean Difference IV, Random, 95% CI
Mora 2013 (1)	3.9	2.19	29	3.89	2.5	27	13.4%	0.00 [-0.52 , 0.53]
NCT00066937 (2)	2.7	2.1	16	2	1.4	26	10.6%	0.40 [-0.22 , 1.03]
NCT00066937 (3)	2.7	2.1	17	2.8	2.1	19	10.1%	-0.05 [-0.70 , 0.61]
Turk 1993 (1)	2.4	1.2	30	1.6	1.2	28	13.3%	0.66 [0.13 , 1.19]
Turner 2006 (4)	5.2	1.9	72	5.2	2.1	76	21.3%	0.00 [-0.32 , 0.32]
Turner 2011 (5)	3.1	1.8	59	3.6	2.2	28	15.9%	-0.26 [-0.71 , 0.20]
Turner 2011 (6)	2.9	2	55	3.6	2.2	27	15.4%	-0.34 [-0.80 , 0.13]
Total (95% CI)			**278**			**231**	**100.0%**	**0.03 [-0.21 , 0.28]**

Heterogeneity: Tau² = 0.05; Chi² = 10.75, df = 6 (P = 0.10); I² = 44%
Test for overall effect: Z = 0.27 (P = 0.79)
Test for subgroup differences: Not applicable

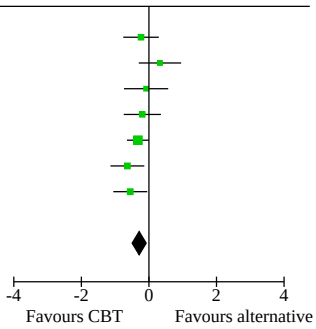


Footnotes
(1) CBT versus intra-oral appliance
(2) Half of CBT plus placebo versus disease management plus nortriptyline
(3) Half of CBT plus placebo versus disease management plus placebo
(4) CBT versus self-care management
(5) CBT (Self-management) versus half continuous oral contraceptive therapy
(6) CBT (Targeted self-management) versus half continuous oral contraceptive therapy

Analysis 1.2. Comparison 1: CBT versus alternative active intervention, Outcome 2: Pain intensity at follow-up

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Alternative treatment Mean	Alternative treatment SD	Alternative treatment Total	Weight	Std. Mean Difference IV, Random, 95% CI
Mora 2013	3.62	2.48	29	4.21	2.5	27	13.1%	-0.23 [-0.76 , 0.29]
NCT00066937 (1)	2	2.1	16	1.4	1.6	26	9.7%	0.33 [-0.30 , 0.95]
NCT00066937 (2)	2	2.1	17	2.2	2.5	19	9.0%	-0.08 [-0.74 , 0.57]
Turk 1993	2	1.3	26	2.3	1.7	25	12.2%	-0.20 [-0.75 , 0.35]
Turner 2006	3.9	2.6	72	4.7	2.3	76	27.6%	-0.32 [-0.65 , -0.00]
Turner 2011 (3)	2.8	1.6	48	3.9	1.9	24	14.2%	-0.64 [-1.14 , -0.14]
Turner 2011 (4)	2.8	2	46	3.9	1.9	24	14.2%	-0.55 [-1.06 , -0.05]
Total (95% CI)			**254**			**221**	**100.0%**	**-0.29 [-0.50 , -0.08]**

Heterogeneity: Tau² = 0.01; Chi² = 7.19, df = 6 (P = 0.30); I² = 17%
Test for overall effect: Z = 2.74 (P = 0.006)
Test for subgroup differences: Not applicable

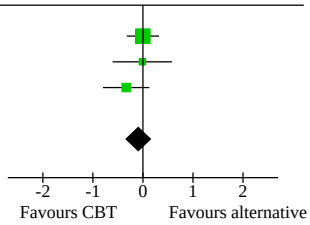


Footnotes
(1) Half of CBT plus placebo versus disease management plus nortriptyline
(2) Half of CBT plus placebo versus disease management plus placebo
(3) Targeted self-management (CBT) versus half continuous oral contraceptive therapy
(4) Self-management (CBT) versus half continuous oral contraceptive therapy

Analysis 1.3. Comparison 1: CBT versus alternative active intervention, Outcome 3: Pain intensity at completion (sensitivity analysis structured diagnosis only)

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Alternative Mean	Alternative SD	Alternative Total	Weight	Std. Mean Difference IV, Random, 95% CI
Turner 2006	5.2	1.9	72	5.2	2.1	76	56.2%	0.00 [-0.32 , 0.32]
Turner 2011 (1)	3.1	59	18	3.6	2.2	28	16.6%	-0.01 [-0.61 , 0.58]
Turner 2011 (2)	2.9	2	55	3.6	2.2	27	27.2%	-0.34 [-0.80 , 0.13]
Total (95% CI)			**145**			**131**	**100.0%**	**-0.09 [-0.33 , 0.15]**

Heterogeneity: Tau² = 0.00; Chi² = 1.44, df = 2 (P = 0.49); I² = 0%
Test for overall effect: Z = 0.76 (P = 0.45)
Test for subgroup differences: Not applicable

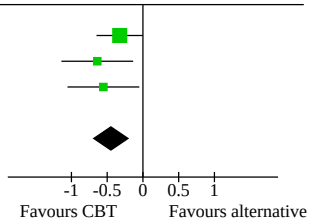


Footnotes
(1) Self-management (CBT) versus half continuous oral contraceptive therapy
(2) Targeted self-management (CBT) versus half continuous oral contraceptive therapy

Analysis 1.4. Comparison 1: CBT versus alternative active intervention, Outcome 4: Pain intensity at follow-up (sensitivity analysis structured diagnosis only)

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Alternative Mean	Alternative SD	Alternative Total	Weight	Std. Mean Difference IV, Random, 95% CI
Turner 2006	3.9	2.6	72	4.7	2.3	76	54.5%	-0.32 [-0.65 , -0.00]
Turner 2011 (1)	2.8	1.6	48	3.9	1.9	24	22.8%	-0.64 [-1.14 , -0.14]
Turner 2011 (2)	2.8	2	46	3.9	1.9	24	22.7%	-0.55 [-1.06 , -0.05]
Total (95% CI)			**166**			**124**	**100.0%**	**-0.45 [-0.69 , -0.21]**

Heterogeneity: Tau² = 0.00; Chi² = 1.28, df = 2 (P = 0.53); I² = 0%
Test for overall effect: Z = 3.67 (P = 0.0002)
Test for subgroup differences: Not applicable

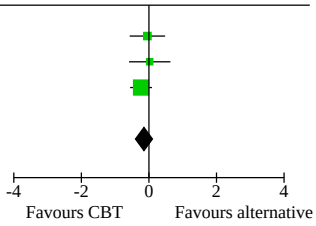


Footnotes
(1) Targeted self-management (CBT) versus half continuous oral contraceptive therapy
(2) Self-management (CBT) versus half continuous oral contraceptive therapy

Analysis 1.5. Comparison 1: CBT versus alternative active intervention, Outcome 5: Pain disability at treatment completion

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Alternative treatment Mean	Alternative treatment SD	Alternative treatment Total	Weight	Std. Mean Difference IV, Random, 95% CI
Mora 2013	11.07	12.01	29	11.62	12.26	27	22.9%	-0.04 [-0.57 , 0.48]
Turk 1996	1.75	1.08	21	1.72	1.36	20	16.8%	0.02 [-0.59 , 0.64]
Turner 2006	1.4	0.9	72	1.6	0.8	76	60.3%	-0.23 [-0.56 , 0.09]
Total (95% CI)			**122**			**123**	**100.0%**	**-0.15 [-0.40 , 0.10]**

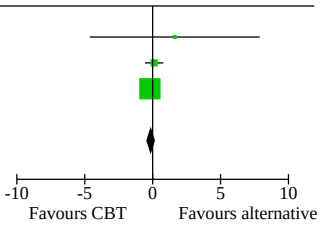
Heterogeneity: Tau² = 0.00; Chi² = 0.72, df = 2 (P = 0.70); I² = 0%
Test for overall effect: Z = 1.15 (P = 0.25)
Test for subgroup differences: Not applicable



Analysis 1.6. Comparison 1: CBT versus alternative active intervention, Outcome 6: Pain disability at follow-up

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Alternative treatment Mean	Alternative treatment SD	Alternative treatment Total	Weight	Mean Difference IV, Random, 95% CI
Mora 2013	13.24	11.96	29	11.61	11.91	27	0.2%	1.63 [-4.63 , 7.89]
Turk 1996	1.24	1.03	21	1.13	1.17	20	15.8%	0.11 [-0.57 , 0.79]
Turner 2006	1.3	1	72	1.5	0.8	76	84.1%	-0.20 [-0.49 , 0.09]
Total (95% CI)			**122**			**123**	**100.0%**	**-0.15 [-0.42 , 0.12]**

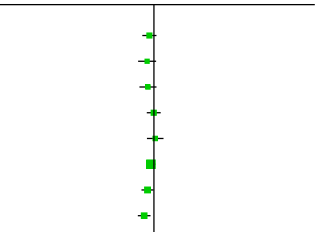
Heterogeneity: Tau² = 0.00; Chi² = 0.99, df = 2 (P = 0.61); I² = 0%
Test for overall effect: Z = 1.08 (P = 0.28)
Test for subgroup differences: Not applicable



Analysis 1.7. Comparison 1: CBT versus alternative active intervention, Outcome 7: Psychological distress at treatment completion

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Alternative treatment Mean	Alternative treatment SD	Alternative treatment Total	Weight	Std. Mean Difference IV, Random, 95% CI
Mora 2013	13.05	8.88	29	16.09	8.95	28	10.9%	-0.34 [-0.86 , 0.19]
NCT00066937 (1)	48.4	8.1	17	53.3	10.6	19	6.8%	-0.50 [-1.17 , 0.16]
NCT00066937 (2)	48.4	8.1	16	52.6	10	26	7.6%	-0.44 [-1.07 , 0.19]
Turk 1993	11.4	6.9	30	11.5	6.4	28	11.2%	-0.01 [-0.53 , 0.50]
Turk 1996	6.86	5.37	21	6.35	5.11	20	8.0%	0.10 [-0.52 , 0.71]
Turner 2006	8.8	9.3	72	11	10.6	76	27.4%	-0.22 [-0.54 , 0.10]
Turner 2011 (3)	4	5.4	59	6.9	7.3	29	14.6%	-0.47 [-0.92 , -0.02]
Turner 2011 (4)	2.9	4.3	55	6.9	7.3	28	13.5%	-0.72 [-1.19 , -0.25]
Total (95% CI)			**299**			**254**	**100.0%**	**-0.32 [-0.50 , -0.15]**

Heterogeneity: Tau² = 0.00; Chi² = 7.20, df = 7 (P = 0.41); I² = 3%
Test for overall effect: Z = 3.64 (P = 0.0003)
Test for subgroup differences: Not applicable



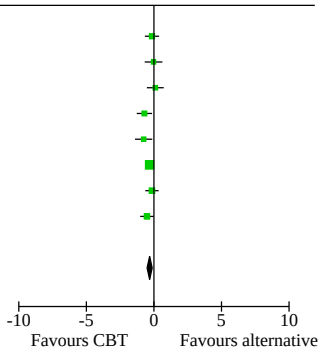
Footnotes

(1) Half of CBT plus placebo versus disease management plus nortriptyline
(2) Half of CBT plus placebo versus disease management plus placebo
(3) Self-management (CBT) versus half continuous oral contraceptive therapy
(4) Targeted self-management (CBT) versus half continuous oral contraceptive therapy

Analysis 1.8. Comparison 1: CBT versus alternative active intervention, Outcome 8: Psychological distress at follow-up

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Alternative treatment Mean	Alternative treatment SD	Alternative treatment Total	Weight	Std. Mean Difference IV, Random, 95% CI
Mora 2013	15.05	11.86	29	16.67	10.07	27	11.8%	-0.14 [-0.67 , 0.38]
NCT00066937 (1)	53.3	12.8	17	53.6	7.3	19	7.8%	-0.03 [-0.68 , 0.63]
NCT00066937 (2)	53.3	12.8	16	52.3	7.2	26	8.6%	0.10 [-0.52 , 0.72]
Turk 1993	10.8	5.4	26	16.3	9.5	25	10.2%	-0.70 [-1.27 , -0.14]
Turk 1996	4.29	3.47	21	7.3	4.27	20	8.2%	-0.76 [-1.40 , -0.12]
Turner 2006	8.3	9.1	72	11.4	10.1	76	27.3%	-0.32 [-0.64 , 0.00]
Turner 2011 (3)	5.1	5.3	48	6	7.6	24	13.3%	-0.14 [-0.64 , 0.35]
Turner 2011 (4)	3	4.5	46	6	7.6	24	12.8%	-0.52 [-1.02 , -0.02]
Total (95% CI)			**275**			**241**	**100.0%**	**-0.32 [-0.51 , -0.13]**

Heterogeneity: Tau² = 0.01; Chi² = 7.64, df = 7 (P = 0.37); I² = 8%
Test for overall effect: Z = 3.32 (P = 0.0009)
Test for subgroup differences: Not applicable



Footnotes
(1) Half of CBT plus placebo versus disease management plus placebo
(2) Half of CBT plus placebo versus disease management plus nortriptyline
(3) Self-management (CBT) versus half continuous oral contraceptive therapy
(4) Targeted self-management (CBT) versus half continuous oral contraceptive therapy

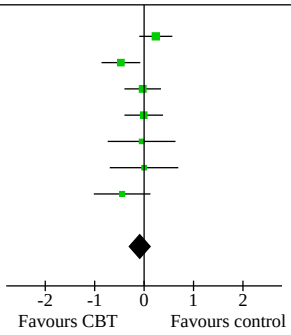
Comparison 2. CBT versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Pain intensity at completion	6	577	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.30, 0.12]
2.2 Pain intensity at follow-up	6	639	Std. Mean Difference (IV, Random, 95% CI)	-0.30 [-0.51, -0.09]
2.3 Pain disability at completion	3	315	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.21, 0.24]
2.4 Pain disability at follow-up	2	240	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.61, 0.64]
2.5 Psychological distress at completion	1	101	Mean Difference (IV, Random, 95% CI)	2.36 [-1.17, 5.89]
2.6 Psychological distress at follow-up	1	101	Mean Difference (IV, Fixed, 95% CI)	-1.02 [-4.02, 1.98]

Analysis 2.1. Comparison 2: CBT versus control, Outcome 1: Pain intensity at completion

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Dworkin 1994	3.73	2.6486	73	3.14	2.2747	66	20.8%	0.24 [-0.10 , 0.57]
Dworkin 2002a	4.2	2.96	52	5.6	2.96	51	17.4%	-0.47 [-0.86 , -0.08]
Dworkin 2002b	3	3.5	61	3.1	3.5	52	18.6%	-0.03 [-0.40 , 0.34]
Litt 2010	2.71	1.42	52	2.72	1.33	49	17.5%	-0.01 [-0.40 , 0.38]
Mishra 2000 (1)	41.51	16.83	22	42.53	23.56	13	7.8%	-0.05 [-0.74 , 0.63]
Mishra 2000 (2)	42.5	15.11	24	42.53	23.56	12	7.6%	-0.00 [-0.69 , 0.69]
Turk 1993	2.4	1.2	30	3	1.5	20	10.3%	-0.45 [-1.02 , 0.13]
Total (95% CI)			**314**			**263**	**100.0%**	**-0.09 [-0.30 , 0.12]**

Heterogeneity: Tau² = 0.03; Chi² = 9.07, df = 6 (P = 0.17); I² = 34%
Test for overall effect: Z = 0.83 (P = 0.41)
Test for subgroup differences: Not applicable

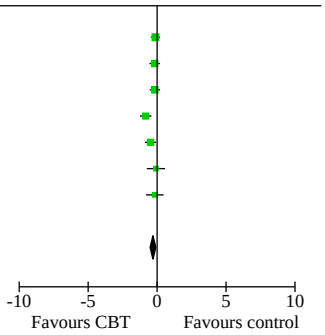


Footnotes
(1) CBT skills versus half of control
(2) CBT plus biofeedback versus half of control

Analysis 2.2. Comparison 2: CBT versus control, Outcome 2: Pain intensity at follow-up

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Dworkin 1994	2.74	2.7341	73	3.03	2.1935	66	19.2%	-0.12 [-0.45 , 0.22]
Dworkin 2002a	4.1	2.32	56	4.5	2.32	51	16.7%	-0.17 [-0.55 , 0.21]
Dworkin 2002b	2.2	4.84	61	3	4.84	51	17.1%	-0.16 [-0.54 , 0.21]
Gatchel 2006	22.44	17.49	54	33.3	2	45	15.1%	-0.83 [-1.24 , -0.42]
Litt 2010	2.14	1.19	52	2.73	1.28	49	15.9%	-0.47 [-0.87 , -0.08]
Mishra 2000 (1)	31.4	75	24	38.4	86.9	14	7.8%	-0.09 [-0.75 , 0.57]
Mishra 2000 (2)	27.2	49.9	29	38.4	86.9	14	8.2%	-0.17 [-0.81 , 0.47]
Total (95% CI)			**349**			**290**	**100.0%**	**-0.30 [-0.51 , -0.09]**

Heterogeneity: Tau² = 0.03; Chi² = 9.74, df = 6 (P = 0.14); I² = 38%
Test for overall effect: Z = 2.85 (P = 0.004)
Test for subgroup differences: Not applicable

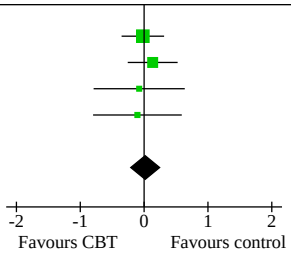


Footnotes
(1) Cognitive Skills group vs half of control
(2) Combined cognitive and biofeedback group vs half of control

Analysis 2.3. Comparison 2: CBT versus control, Outcome 3: Pain disability at completion

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Dworkin 1994	2.11	2.6486	73	2.16	2.356	66	46.0%	-0.02 [-0.35 , 0.31]
Litt 2010	1.53	1.29	52	1.36	1.22	49	33.4%	0.13 [-0.26 , 0.52]
Mishra 2000 (1)	1.19	1.65	24	1.36	3.01	11	10.0%	-0.08 [-0.79 , 0.64]
Mishra 2000 (2)	1.13	1.75	29	1.36	3.01	11	10.6%	-0.10 [-0.80 , 0.59]
Total (95% CI)			**178**			**137**	**100.0%**	**0.02 [-0.21 , 0.24]**

Heterogeneity: Tau² = 0.00; Chi² = 0.58, df = 3 (P = 0.90); I² = 0%
Test for overall effect: Z = 0.15 (P = 0.88)
Test for subgroup differences: Not applicable

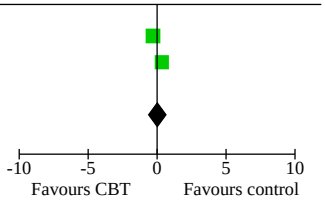


Footnotes
(1) CBT skills versus half of control
(2) CBT plus biofeedback versus half of control

Analysis 2.4. Comparison 2: CBT versus control, Outcome 4: Pain disability at follow-up

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Dworkin 1994	1.09	1.8797	73	1.75	2.5185	66	51.4%	-0.30 [-0.63 , 0.04]
Litt 2010	1.87	1.47	52	1.42	1.11	49	48.6%	0.34 [-0.05 , 0.73]
Total (95% CI)			**125**			**115**	**100.0%**	**0.01 [-0.61 , 0.64]**

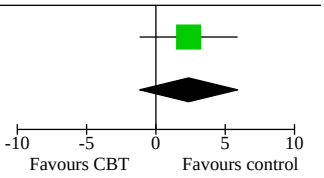
Heterogeneity: Tau² = 0.17; Chi² = 5.88, df = 1 (P = 0.02); I² = 83%
Test for overall effect: Z = 0.04 (P = 0.97)
Test for subgroup differences: Not applicable



Analysis 2.5. Comparison 2: CBT versus control, Outcome 5: Psychological distress at completion

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
Litt 2010	12.78	9.79	52	10.42	8.3	49	100.0%	2.36 [-1.17 , 5.89]
Total (95% CI)			**52**			**49**	**100.0%**	**2.36 [-1.17 , 5.89]**

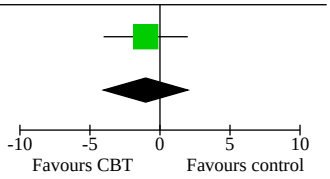
Heterogeneity: Not applicable
Test for overall effect: Z = 1.31 (P = 0.19)
Test for subgroup differences: Not applicable



Analysis 2.6. Comparison 2: CBT versus control, Outcome 6: Psychological distress at follow-up

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
Litt 2010	10.7	7	52	11.72	8.3	49	100.0%	-1.02 [-4.02 , 1.98]
Total (95% CI)			**52**			**49**	**100.0%**	**-1.02 [-4.02 , 1.98]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.67 (P = 0.51)
Test for subgroup differences: Not applicable



ADDITIONAL TABLES

Table 1. Pain reduction from baseline (30% reduction threshold)

Study	Intervention	Comparison	At treatment completion		At follow-up	
			Intervention	Control	Intervention	Control
Abrahamsen 2011	Hypnosis	Relaxation	✓ 36%	# 7%	-	-
Bartley 2019	Hope based	Pain education	# 15%	# 13%	-	-
Calderon 2011[1,2]	CBT + placebo	Placebo	✓	✓	✓	✓

Table 1. Pain reduction from baseline (30% reduction threshold) *(Continued)*

			73%	45%	49%	32%
Dworkin 1994	CBT	Usual care	# 28%	✓ 31%	✓ 47%	✓ 33%
Dworkin 2002a [1]	CBT	Usual care	✓ 38%	# 18%	✓ 40%	✓ 34%
Dworkin 2002b[1]	CBT	Usual care	✓ 36%	✓ 31%	✓ 51%	✓ 33%
Ferrando 2012	CBT + hypnosis	Usual care	✓ 51%	# 16%	✓ 55%	✓
Gatchel 2006	CBT/biofeedback	Usual care	-	-	✓ 62%	✓ 42%
NCT00066937[3]	CBT + placebo	Disease management + placebo	✓ 39%	✓ 44%	✓ 55%	✓ 56%
		Disease management + nortriptyline		✓ 56%		✓ 69%
Litt 2010[4]	CBT	Usual care	#	#	#	#
Lupton 1968	Education	Usual care	-	-	-	-
	Counselling		-	-	-	-
Mishra 2000[5]	CBT	Waiting-list control	# 23%	# 11%	✓ 33%	# 21%
	CBT/biofeedback		# 26%		✓ 51%	
Mora 2013	CBT/biofeedback	Intraoral appliance	# 28%	✓ 30%	✓ 33%	# 24%
Shevtsova 2020	Mindfulness + medication	Medication alone	✓	✓	✓	✓
Stam 1984[6]	Hypnosis	Relaxation	# 27%	✓ 31%	-	-
Townsend 2001	Habit reversal	Waiting-list control	✓ 46%	# -6%	✓ 58%	-
Turk 1993[7]	CBT	Intraoral appliance	#	✓	✓	✓

Table 1. Pain reduction from baseline (30% reduction threshold) *(Continued)*

			29%	54%	41%	34%
Turk 1996[8]	CBT	Non-directive counselling	-	-	-	-
Turner 2006	CBT	Self-care management	# 24%	# 24%	✓ 42%	✓ 31%
Turner 2011	CBT/self-care management	Oral contraceptive	✓ 38%	✓ 32%	✓ 44%	# 26%
	CBT/targeted		✓ 42%		✓ 44%	
Wahlund 2003[1,9]	Relaxation	Oral appliance	#	✓	#	✓
Wahlund 2015	Relaxation	Oral appliance	# 22%	✓ 37%	-	-

✓ = ≥ 30% reduction in pain from baseline
= < 30% reduction in pain from baseline
CBT: cognitive behaviour therapy

[1]Data not suitable for meta-analysis.
[2]Other treatment arms (not presented here): CBT plus amitriptyline, amitriptyline alone.
[3]Other treatment arm (not presented here): CBT + nortriptyline. Benztropine used as placebo.
[4]Baseline data not presented; unable to calculate % reduction.
[5]Biofeedback only group (not presented here) also evaluated but the difference between the CBT and biofeedback groups was not clear.
[6]Waiting-list control arm (not presented here) showed an increase in pain.
[7]Waiting-list control also evaluated but data only available until end of treatment.
[8]Both groups also received splint.
[9]Both groups also received behavioural intervention.

Table 2. Data on pain intensity presented in studies that could not be combined in meta-analyses due to treatment heterogeneity

Study and comparison	MD from baseline to treatment completion	% change	SD	n	MD (95% CI)
Abrahamsen 2011					
Hypnosis	2.9	36	2.4	19	-1.00 (-2.27 to 0.27)
Relaxation	3.9	7	1.5	19	
Bartley 2019					
Hope-based intervention	33.5	15	18.7	15	0.10 (-13.52 to 13.72)
Pain education	33.4	13	18.7	14	

Table 2. Data on pain intensity presented in studies that could not be combined in meta-analyses due to treatment heterogeneity *(Continued)*

Ferrando 2012					
CBT/hypnosis	2.92	51	2.03	30	-2.32 (-3.52 to -1.12)
Usual care	5.24	16	2.61	29	
Stam 1984					
Hypnosis	44.8	27	not reported	12	not reported
Relaxation	34.9	31		15	
Townsend 2001					
Habit-reversal treatment	0.96	46	0.57	10	-1.31 (-1.97 to -0.65)
Waiting-list control	2.27	6*	0.89	10	
Wahlund 2003					
Relaxation	not reported	35	not reported	41	not reported
Oral appliance		51		42	
Wahlund 2015					
Relaxation	18.4	22	9.5	28	3.70 (-1.21 to 8.61)
Oral appliance	14.7	37	9.4	29	

CBT: cognitive behaviour therapy; MD: mean difference; SD: standard deviation
*pain increased from baseline

APPENDICES

Appendix 1. Cochrane Oral Health's Trials Register search strategy

Cochrane Oral Health's Trials Register is available via the Cochrane Register of Studies. For information on how the register is compiled, see oralhealth.cochrane.org/trials.

1. MESH DESCRIPTOR Craniomandibular Disorders EXPLODE ALL AND INREGISTER
2. MESH DESCRIPTOR Facial Pain AND INREGISTER
3. (temporomandibular or "temporo mandibular") AND INREGISTER
4. (TMJ or TMD or TMJD) AND INREGISTER
5. ((TM or TMJ) near1 (disorder* or dysfunction* or disease*)) AND INREGISTER
6. ((facial or face or orofacial or "oro facial") near2 (pain* or neuralgia)) AND INREGISTER
7. #1 or #2 or #3 or #4 or #5 or #6 AND INREGISTER
8. MESH DESCRIPTOR Psychotherapy EXPLODE ALL AND INREGISTER
9. MESH DESCRIPTOR Adaptation, Psychological AND INREGISTER
10. MESH DESCRIPTOR Relaxation Therapy AND INREGISTER
11. ((cognitive or cognition) near3 (behav* or treatment* or technique* or therap* or intervention* or restructur* or reapprais*)) AND INREGISTER

12. (behav* near3 (treatment* or therap* or intervention* or activ* or technique* or modif* or change* or adapt* or condition*)) AND INREGISTER
13. (accept* near5 commitment) AND INREGISTER
14. (autogenic near1 (train* or relax*)) AND INREGISTER
15. (mindful* or awareness or mood*) AND INREGISTER
16. "conditioning therap*" AND INREGISTER
17. ((adapt* or cope or coping) near3 behavi*) AND INREGISTER
18. (coping near3 (skill* or strateg*)) AND INREGISTER
19. (psychotherap* or psychological*) AND INREGISTER
20. (group* near3 (therap* or psychotherap*)) AND INREGISTER
21. (talk* near3 (therap* or intervention*)) AND INREGISTER
22. MESH DESCRIPTOR Counseling AND INREGISTER
23. counsel* AND INREGISTER
24. #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 AND INREGISTER
25. #24 AND #7 AND INREGISTER

Appendix 2. Cochrane Central Register of Controlled Trials (CENTRAL) search strategy

1. MESH DESCRIPTOR Craniomandibular Disorders EXPLODE ALL AND CENTRAL:TARGET
2. MESH DESCRIPTOR Facial Pain AND CENTRAL:TARGET
3. (temporomandibular or "temporo mandibular") AND CENTRAL:TARGET
4. (TMJ or TMD or TMJD) AND CENTRAL:TARGET
5. ((TM or TMJ) near1 (disorder* or dysfunction* or disease*)) AND CENTRAL:TARGET
6. ((facial or face or orofacial or "oro facial") near2 (pain* or neuralgia)) AND CENTRAL:TARGET
7. #1 or #2 or #3 or #4 or #5 or #6 AND CENTRAL:TARGET
8. MESH DESCRIPTOR Psychotherapy EXPLODE ALL AND CENTRAL:TARGET
9. MESH DESCRIPTOR Adaptation, Psychological AND CENTRAL:TARGET
10. MESH DESCRIPTOR Relaxation Therapy AND CENTRAL:TARGET
11. ((cognitive or cognition) near3 (behav* or treatment* or technique* or therap* or intervention* or restructur* or reapprais*)) AND CENTRAL:TARGET
12. (behav* near3 (treatment* or therap* or intervention* or activ* or technique* or modif* or change* or adapt* or condition*)) AND CENTRAL:TARGET
13. (accept* near5 commitment) AND CENTRAL:TARGET
14. (autogenic near1 (train* or relax*)) AND CENTRAL:TARGET
15. (mindful* or awareness or mood*) AND CENTRAL:TARGET
16. "conditioning therap*" AND CENTRAL:TARGET
17. ((adapt* or cope or coping) near3 behavi*) AND CENTRAL:TARGET
18. (coping near3 (skill* or strateg*)) AND CENTRAL:TARGET
19. (psychotherap* or psychological*) AND CENTRAL:TARGET
20. (group* near3 (therap* or psychotherap*)) AND CENTRAL:TARGET
21. (talk* near3 (therap* or intervention*)) AND CENTRAL:TARGET
22. MESH DESCRIPTOR Counseling AND CENTRAL:TARGET
23. counsel* AND CENTRAL:TARGET
24. #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 AND CENTRAL:TARGET
25. #24 AND #7 AND CENTRAL:TARGET

Appendix 3. MEDLINE Ovid search strategy

1. exp craniomandibular disorders/
2. Facial pain/
3. (temporomandibular or "temporo mandibular").mp.
4. (TMJ or TMD or TMJD).ti,ab.
5. ((TM or TMJ) adj (disorder$ or dysfunction$ or disease$)).mp.
6. ((facial or face or orofacial or "oro facial") adj2 (pain$ or neuralgia)).mp.
7. or/1-6

8. exp Psychotherapy/
9. Adaptation, psychological/
10. Relaxation therapy/
11. ((cognitive or cognition) adj3 (behav$ or treatment$ or technique$ or therap$ or intervention$ or restructur$ or reapprais$)).mp.
12. (behav$ adj3 (treatment$ or therap$ or intervention$ or activ$ or technique$ or modif$ or change$ or adapt$ or condition$)).mp.
13. (accept$ adj5 commitment).mp.
14. (autogenic adj (train$ or relax$)).mp.
15. (mindful$ or awareness or mood$).mp.
16. "conditioning therap$".mp.
17. ((adapt$ or cope or coping) adj3 behavi$).mp.
18. (coping adj3 (skill$ or strateg$)).mp.
19. (psychotherap$ or psychological$).mp.
20. (group$ adj3 (therap$ or psychotherap$)).mp.
21. (talk$ adj3 (therap$ or intervention$)).mp.
22. counseling/
23. counsel$.mp.
24. or/8-23
25. 7 and 24

The above subject search will be linked with the highly sensitive search strategy designed by Cochrane for identifying randomised controlled trials and controlled clinical trials (as described in the *Cochrane Handbook for Systematic Reviews of Interventions* Box 6.4.b (Lefebvre 2020)).

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

Appendix 4. Embase Ovid search strategy

1. Temporomandibular joint disorder/
2. Face pain/
3. (temporomandibular or "temporo mandibular").mp.
4. (TMJ or TMD or TMJD).ti,ab.
5. ((TM or TMJ) adj (disorder$ or dysfunction$ or disease$)).mp.
6. ((facial or face or orofacial or "oro facial") adj2 (pain$ or neuralgia)).mp.
7. or/1-6
8. exp Psychotherapy/
9. exp Coping behavior/
10. ((cognitive or cognition) adj3 (behav$ or treatment$ or technique$ or therap$ or intervention$ or restructur$ or reapprais$)).mp.
11. (behav$ adj3 (treatment$ or therap$ or intervention$ or activ$ or technique$ or modif$ or change$ or adapt$ or condition$)).mp.
12. (accept$ adj5 commitment).mp.
13. (autogenic adj (train$ or relax$)).mp.
14. (mindful$ or awareness or mood$).mp.
15. "conditioning therap$".mp.
16. ((adapt$ or cope or coping) adj3 behavi$).mp.
17. (coping adj3 (skill$ or strateg$)).mp.
18. (psychotherap$ or psychological$).mp.

19.(group$ adj3 (therap$ or psychotherap$)).mp.
20.(talk$ adj3 (therap$ or intervention$)).mp.
21.exp counseling/
22.counsel$.mp.
23.or/8-22
24.7 and 23

The above subject search was linked with the highly sensitive search strategy designed by Cochrane for identifying randomised controlled trials and controlled clinical trials in Embase (as described in Lefebvre 2020, box 3e).

1. Randomized controlled trial/
2. Controlled clinical study/
3. random$.ti,ab.
4. randomization/
5. intermethod comparison/
6. placebo.ti,ab.
7. (compare or compared or comparison).ti.
8. ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab.
9. (open adj label).ti,ab.
10.((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab.
11.double blind procedure/
12.parallel group$1.ti,ab.
13.(crossover or cross over).ti,ab.
14.((assign$ or match or matched or allocation) adj5 (alternate or group$1 or intervention$1 or patient$1 or subject$1 or participant $1)).ti,ab.
15.(assigned or allocated).ti,ab.
16.(controlled adj7 (study or design or trial)).ti,ab.
17.(volunteer or volunteers).ti,ab.
18.human experiment/
19.trial.ti.
20.or/1-19
21.random$ adj sampl$ adj7 ("cross section$" or questionnaire$1 or survey$ or database$1)).ti,ab. not (comparative study/ or controlled study/ or randomi?ed controlled.ti,ab. or randomly assigned.ti,ab.)
22.Cross-sectional study/ not (randomized controlled trial/ or controlled clinical study/ or controlled study/ or randomi?ed controlled.ti,ab. or control group$1.ti,ab.)
23.(((case adj control$) and random$) not randomi?ed controlled).ti,ab.
24.(Systematic review not (trial or study)).ti.
25.(nonrandom$ not random$).ti,ab.
26."Random field$".ti,ab.
27.(random cluster adj3 sampl$).ti,ab.
28.(review.ab. and review.pt.) not trial.ti.
29."we searched".ab. and (review.ti. or review.pt.)
30."update review".ab.
31.(databases adj4 searched).ab.
32.(rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset$1).ti. and animal experiment/
33.Animal experiment/ not (human experiment/ or human/)
34.or/21-33
35.20 not 34

Appendix 5. PsycINFO Ovid search strategy

PsycINFO Ovid search strategy

1. Joint disorders/
2. Jaw/

3. 1 and 2
4. (temporomandibular or "temporo mandibular").mp.
5. (TMJ or TMD or TMJD).ti,ab.
6. ((TM or TMJ) adj (disorder$ or dysfunction$ or disease$)).mp.
7. ((facial or face or orofacial or "oro facial") adj2 (pain$ or neuralgia)).mp.
8. 3 or 4 or 5 or 6 or 7
9. exp Psychotherapy/
10. exp Coping behavior/
11. Relaxation therapy/
12. ((cognitive or cognition) adj3 (behav$ or treatment$ or technique$ or therap$ or intervention$ or restructur$ or reapprais$)).mp.
13. (behav$ adj3 (treatment$ or therap$ or intervention$ or activ$ or technique$ or modif$ or change$ or adapt$ or condition$)).mp.
14. (accept$ adj5 commitment).mp.
15. (autogenic adj (train$ or relax$)).mp.
16. (mindful$ or awareness or mood$).mp.
17. "conditioning therap$".mp.
18. ((adapt$ or cope or coping) adj3 behavi$).mp.
19. (coping adj3 (skill$ or strateg$)).mp.
20. (psychotherap$ or psychological$).mp.
21. (group$ adj3 (therap$ or psychotherap$)).mp.
22. (talk$ adj3 (therap$ or intervention$)).mp.
23. exp counseling/
24. counsel$.mp.
25. or/9-24
26. 8 and 25

The subject search was linked to the Cochrane Oral Health filter for PsycINFO:

1. exp clinical trials/
2. (clin$ adj25 trial$).ti,ab.
3. placebo$.ti,ab.
4. random$.ti,ab.
5. ((randomised adj controlled adj trial$) or (randomized adj controlled adj trial$)).mp.
6. (controlled adj clinical adj trial$).mp.
7. (random adj allocat$).mp.
8. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
9. (control$ adj4 trial$).mp.
10. (ANIMALS not HUMANS).sh.
11. or/1-9
12. 11 not 10

Appendix 6. Trip database search strategy

With all the words: (temporomandibular)

With any of the words: psychological or psychotherapy or cognitive or behavior or behaviour or mindfulness or mood or counselling

Appendix 7. Web of Science Conference Proceedings search strategy

20 #18 and #19
19 TS=(trial* or random* or placebo*)
18 #4 and #17
17 #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16
16 TS=counsel*
15 TS=(talk* AND (therap* or intervention*))
14 TS=(group* AND (therap* or psychotherap*))
13 TS=(psychotherap* or psychological*)
12 TS=(coping AND (skill* or strateg*))

11 TS=((adapt* or cope or coping) AND behavi*)
10 TS="conditioning therap*"
9 TS=(mindful* or awareness or mood*)
8 TS=(autogenic and (train* or relax*))
7 TS=(accept* and commitment)
6 TS=(behav* AND (treatment* or therap* or intervention* or activ* or technique* or modif* or change* or adapt* or condition*))
5 TS=((cognitive or cognition) AND (behav* or treatment* or technique* or therap* or intervention* or restructur* or reapprais*))
4 #1 or #2 or #3
3 TI=(TMJ or TMD or TJMD)
2 TS=((face or facial or orofacial or "oro facial") AND (pain or neuralgia))
1 TS=(temporomandibular or "temporo mandibular")

Appendix 8. Proquest Disserations and Theses Global search strategy

noft(temporomandibular OR "temporomandibular" OR "facial pain" OR "orofacial pain") AND noft(psychotherap* OR "relaxation therap*" OR psychological* OR cognitiv* OR cognition OR behaviour* OR behavior* OR autogenic OR commitment OR awareness OR mood OR mindful* OR "conditioning therap*" OR adapt* OR cope OR coping OR "group therap*" OR psychotherap* OR counsel*) AND noft(random* or trial* or placebo*)

Appendix 9. Open Grey search strategy

temporomandibular and psycho*

Appendix 10. US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov) search strategy

Expert search:

temporomandibular AND (psychotherap* OR "relaxation therap*" OR psychological* OR cognitiv* OR cognition OR behaviour* OR behavior* OR autogenic OR commitment OR awareness OR mood OR mindful* OR "conditioning therap*" OR adapt* OR cope OR coping OR "group therap*" OR psychotherap* OR counsel*)

Appendix 11. World Health Organization International Clinical Trials Registry Platform search strategy

(temporomandibular AND psychotherap* OR temporomandibular AND "relaxation therap*" OR temporomandibular AND psychological* OR temporomandibular AND cognitiv* OR temporomandibular AND cognition OR temporomandibular AND behaviour* OR temporomandibular AND behavior* OR temporomandibular AND autogenic OR temporomandibular AND commitment OR temporomandibular AND awareness OR temporomandibular AND mood OR temporomandibular AND mindful* OR temporomandibular AND "conditioning therap*" OR temporomandibular AND adapt* OR temporomandibular AND cope OR temporomandibular AND coping OR temporomandibular AND "group therap*" OR temporomandibular AND psychotherap* OR temporomandibular AND counsel*)

HISTORY

Protocol first published: Issue 12, 2019

CONTRIBUTIONS OF AUTHORS

Chris Penlington designed the review, screened abstracts and full-text studies, carried out risk of bias assessments, extracted data, carried out GRADE evidence certainty assessments and drafted and revised the full report.
Charlotte Bowes and Greig Taylor, screened abstracts and full-text studies, carried out risk of bias assessments, extracted data and contributed to the full report.
Adetunji Adebowale Otemade, screened abstracts and drafted and revised the full report.
Paula Waterhouse screened abstracts and drafted and revised the full report.
Justin Durham carried out GRADE evidence certainty assessments, commented on and revised the full report.
Richard Ohrbach designed the review, screened full-text studies and commented on and revised the full report.

DECLARATIONS OF INTEREST

Chris Penlington: no conflict of interest
Charlotte Bowes: no conflict of interest
Greig Taylor: is funded by a National Institute for Health Research (NIHR) Doctoral Research Fellowship. The views expressed are his own and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.
Adetunji Adebowale Otemade: no conflict of interest
Paula Waterhouse: no conflict of interest
Justin Durham: no conflict of interest

Richard Ohrbach: is a paid statistical consultant for the Journal of Prosthetic Dentistry and an Associate Editor for the Journal of Oral & Facial Pain and Headache, and he is funded by his university for research-related travel. He receives honoraria and travel reimbursement for speaking engagements based on his published research. Private investments are unrelated to his scholarly activities.

SOURCES OF SUPPORT

Internal sources

- Manchester Academic Health Sciences Centre (MAHSC) and the National Institute for Health Research (NIHR) Manchester Biomedical Research Centre, UK

  Support to Cochrane Oral Health
- Division of Dentistry, School of Medical Sciences, Faculty of Biology, Medicine and Health, The University of Manchester, UK

  Support to Cochrane Oral Health

External sources

- National Institute for Health Research (NIHR), UK

  This project was supported by the NIHR, via Cochrane Infrastructure funding to Cochrane Oral Health. The views and opinions expressed herein are those of the review authors and do not necessarily reflect those of the Evidence Synthesis Programme, the NIHR, the NHS, or the Department of Health and Social Care
- Cochrane Oral Health Global Alliance, Other

  The production of Cochrane Oral Health reviews has been supported financially by our Global Alliance since 2011 (oralhealth.cochrane.org/partnerships-alliances). Contributors in recent years have been the American Association of Public Health Dentistry, USA; AS-Akademie, Germany; the British Association for the Study of Community Dentistry, UK; the British Society of Paediatric Dentistry, UK; the Canadian Dental Hygienists Association, Canada; the Centre for Dental Education and Research at All India Institute of Medical Sciences, India; the National Center for Dental Hygiene Research & Practice, USA; New York University College of Dentistry, USA; and Swiss Society of Endodontology, Switzerland

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

According to the protocol, we had planned to consider separate analyses of cognitive behaviour therapy (CBT), behaviour therapy (BT) and other therapies. We did not do this because only a very small number of studies reported interventions other than CBT. Of these studies, we judged that the high clinical heterogeneity would make it meaningless to consider them in the groupings specified in the original protocol. Instead, we reported all psychological therapies combined and a subset of CBT.

We had intended to include all outcomes in our summary of findings tables, but instead we focused on our primary outcomes and one secondary outcome, 'psychological distress'.

NOTES

This review is based on a protocol published in the Cochrane Library in December 2019 (Penlington 2019c).

INDEX TERMS

Medical Subject Headings (MeSH)

Behavior Therapy; *Cognitive Behavioral Therapy [methods]; Pain; Pain Measurement; Randomized Controlled Trials as Topic; *Temporomandibular Joint Disorders [therapy]

MeSH check words

Adolescent; Adult; Humans